



DEPARTMENT OF THE NAVY
OFFICE OF THE CHIEF OF NAVAL OPERATIONS
2000 NAVY PENTAGON
WASHINGTON, D.C. 20350-2000

IN REPLY REFER TO
3900
Ser N093/14U0098
19 Sep 2014

**Department of Defense – Navy Addendum
to the Federalwide Assurance for the
Protection of Human Research Subjects**

DoD-Navy FWA Addendum: DoD N-A3362

Expiration Date: 15 May 2019

Institution: University of California, San Francisco

The application for the Department of Defense - Navy Addendum to the Federalwide Assurance, FWA00000068, held by the University of California, San Francisco, is approved.

In accordance with the signed Addendum, the University of California, San Francisco and the Institutional Review Board (IRB) listed in the Addendum or in the associated Institutional Agreement(s) for IRB Review, agree to abide by the Department of Defense's and the Department of the Navy's regulations and policies for the protection of human research participants when conducting, reviewing, approving, overseeing, supporting, or managing Navy-supported research with human subjects.

Communications regarding this Addendum should be addressed to:

Bureau of Medicine and Surgery
Skyline Detachment
Department of the Navy
Human Research Protection Program (M00RPH)
7700 Arlington Blvd., Suite 5160
Falls Church, VA 22042-5160
Telephone: 703-681-9629, Fax: 703-681-2597
Email: human.research@med.navy.mil

W. M. DENISTON
Captain, Medical Service Corps
United States Navy
Director, Department of the Navy
Human Research Protection Program
By Direction of the Surgeon General of the Navy

Attachment:

University of California, San Francisco DoD-Navy FWA Addendum application dtd 29 Aug 2014

**Department of Defense
Department of the Navy
Human Research Protection Program**

**DEPARTMENT OF DEFENSE (DOD)-DEPARTMENT OF THE NAVY (DON) ADDENDUM
TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICE'S FEDERAL WIDE
ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS**

This Addendum is for non-DoD Institutions that already have an FWA and will be conducting or collaborating in DoD-DON supported human subject research.

**Part 1
INSTITUTION INFORMATION**

A. Purpose of DoD-DON Addendum: DoD N-A3362

- New
 Renewal for DoD-DON Addendum Number:
 Update for DoD-DON Addendum Number:

DoD-DON Addendum Expiration Date: N/A

B. Institution Information:

Name: University of California, San Francisco
Mailing Address: 3333 California St., Suite 315, San Francisco, CA 94118
Department of Health and Human Services (DHHS) FWA Number: FWA00000068
FWA Expiration Date: 15 May 2019

C. Scope:

This Addendum applies to all DoD-DON supported research protocols performed by this Institution.

D. Effective Date:

This Addendum is effective as of the date the approval document is signed by the DoD Component Designated Official and expires on the date listed in the approval document.

Part 2
DEPARTMENT OF DEFENSE (DOD) REGULATIONS AND GUIDANCE

This institution assures it shall comply with the following laws, regulations, and guidance when conducting, reviewing, approving, overseeing, supporting, or managing DoD-supported research with human subjects:

- The Belmont Report
- Title 32 Code of Federal Regulations Part 219 (32 CFR 219), Department of Defense Regulations, "Protection of Human Subjects"
- Title 45 Code of Federal Regulations Part 46, (45 CFR 46) Department of Health and Human Services Regulations, "Protection of Human Subjects," Subparts B, C, and D as made applicable by DoDI 3216.02
- Title 21 Code of Federal Regulations 50, 56, 312, and 812, Food and Drug Administration (FDA) Regulations
- DoD Instruction (DoDI) 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-supported Research"
- Title 10 United States Code Section 980 (10 USC 980), "Limitation on Use of Humans as Experimental Subjects"
- DoDI 3210.7, "Research Integrity and Misconduct"
- DoDI 6200.02, "Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs"

Part 3
DOD COMPONENT SPECIFIC REQUIREMENTS

Department of the Army

- AR 70-25 Use of Volunteers as Subjects of Research, 25 January 1990
- AR 40-38, Clinical Investigation Program, 1 September 1989
- AR 40-7, Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances, 19 October 2009

Department of the Navy

- SECNAVINST 3900.39D of 6 November 2006

Department of the Air Force

- Air Force Instruction 40-402, Protection of Human Subjects in Research

Office of the Secretary of Defense for Personnel and Readiness

- HA Policy 05-003

Part 4 INSTITUTION RESPONSIBILITIES

Some of the responsibilities of the Institutional Official, IRB, and Investigators are identified below. The complete list of requirements for compliance is provided above in Part 2, DoD Regulations; Part 3, DoD Component Specific Requirement; and Guidance and in the Institution's FWA. The regulations and guidance identified in Part 2 and 3 address such matters as:

- Initial and continuing research ethics education and for all personnel who conduct, review, approve, oversee, support, or manage human subject research
- Written determination by a designated institutional official (other than investigators) whether research meets criteria for exemption
- New research and substantive amendments to approved research shall undergo scientific review prior to ethics (IRB) review
- Additional protections for military research subjects to minimize undue influence
- Provisions for research-related injury
- Requirements for reporting unanticipated problems, adverse events, and research-related injury
- Appointment of a Medical Monitor
- Additional safeguards for research conducted with international populations
- Additional protections for pregnant women, prisoners, and children
- Limitations on research where consent by legally authorized representatives is proposed
- Limitation on exceptions from informed consent in emergency medicine research
- Limitations on dual compensation for U. S. military personnel
- Additional review for DoD-sponsored survey research or survey research within DoD
- Addressing and reporting allegations of non-compliance with human research protections
- Addressing and reporting allegations of research misconduct
- Procedures for addressing conflicting and competing interests
- Prohibition of research with prisoners of war (POW) and detainees
- Provisions for research with human subjects using investigational test articles (drugs, device, and biologics)
- Recordkeeping requirements
- Oversight by the sponsoring DoD Component (which may include DoD Component review of the research and site visits)

Part 5
DESIGNATION OF INSTITUTIONAL REVIEW BOARDS (IRB) THAT WILL REVIEW
DoD-DON-SUPPORTED RESEARCH

A. Institutional IRB(s)

Table 1 identifies the IRB(s) associated with this Institution that will or may review DoD-supported research under this Addendum to the FWA.

For each IRB listed below, the IRB Chair(s) must sign and list the corresponding IRB number(s) in Part 6 of this Institutional Agreement.

Table 1. Institutional IRB(s)

Institutional Name or Number of IRB	DHHS IRB Registration Number
1. Parnassus Committee IRB #1	IRB 00000229
2. San Francisco General Hospital (SFGH) Committee IRB #2	IRB 00000230
3. Laurel Heights Committee (Lhts) IRB #3	IRB 00003471
4. U of California San Francisco IRB #4 - Mt. Zion	IRB 00005096
5.	
6.	

B. IRB(s) not Part of this Institution

Table 2 (if applicable) identifies any IRBs that are not associated with this Institution but will or may review DoD-supported research under this Addendum to the FWA.

For each IRB listed in Table 2, the DoD Institutional Agreement for IRB Review must be attached to this Addendum to the FWA.

Table 2. DoD or non-DoD IRB(s) not Part of this Institution

Name of Institution	DoD Assurance Number	Name or Number of IRB	DHHS/FWA Number	DHHS IRB Registration Number
1.				
2.				
3.				
4.				
5.				
6.				

Part 6
INSTITUTIONAL AGREEMENT

A. Official Legally Authorized to Represent the FWA Institution (i.e., signed the FWA)


Acting in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under my FWA and this Addendum, I assure protections for human subjects as specified above.

Signature: 5911A289858A467...

Date: 8/29/2014

Name: Jeffrey Bluestone, PhD Rank/Grade:
Institutional Title: Executive Vice Chancellor and Provost, UCSF
Telephone number: 415-476-4451 FAX number: 415-476-0816 Email address:
jeffreya.bluestone@ucsf.edu
Mailing Address: 513 Parnassus Ave, Med Sci Room 115, San Francisco, CA 94143

B. Primary Contact - Human Research Protection of the FWA Institution

Signature: 

Date: Aug. 29, 2014

Name: Lisa Denney, MPH Rank/Grade:
Institutional Title: Interim Director, UCSF Human Research Protection Program
Telephone number: 415-514-2152 FAX number: 415-502-1347 Email address:
lisa.denney@ucsf.edu
Mailing Address: 3333 California St., Suite 315, San Francisco, CA 94118

C. Chair(s) of the IRB(s) that will Review DoD-DON Supported Research on behalf of the FWA Institution

Acting in an authorized capacity on behalf of this Institution's IRB(s) and with an understanding of the Institution's responsibilities under its FWA and this Addendum, I assure protections for human subjects as specified above. As Chair of the IRB(s), I shall provide oversight for all research approved by this IRB(s) and conducted under this Addendum.

Signature:



Date:

8/28/14

For IRB #(s): As applicable

Name: Victor Reus, MD Rank/Grade:

Institutional Title: Chair, Parnassus panel of the UCSF Committee on Human Research (IRB)

Telephone number: 415-476-7478 FAX number: 415-476-7404 Email address: victor.reus@ucsf.edu

Mailing Address: 401 Parnassus Ave, Langley Porter Room 469, San Francisco, CA 94143

Note: Each IRB Chair of an IRB reviewing research under this Addendum shall sign and provide the requested information above.

C. Chair(s) of the IRB(s) that will Review DoD-DON Supported Research on behalf of the FWA Institution

Acting in an authorized capacity on behalf of this Institution's IRB(s) and with an understanding of the Institution's responsibilities under its FWA and this Addendum, I assure protections for human subjects as specified above. As Chair of the IRB(s), I shall provide oversight for all research approved by this IRB(s) and conducted under this Addendum.

Signature: *Thomas P. Bersot* Date: *8/26/2014*

For IRB #(s): As applicable

Name: Thomas Bersot, MD, PhD Rank/Grade:

Institutional Title: Chair, SFGH panel of the UCSF Committee on Human Research (IRB)

Telephone number: 415-734-2027 FAX number: 415-355-0919 Email address:

tbersot@gladstone.ucsf.edu

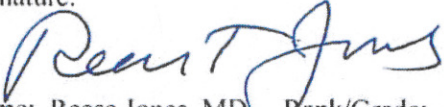
Mailing Address: 1650 Owens Street, Box 1230, Gladstone Institutes, San Francisco, CA 94158

Note: Each IRB Chair of an IRB reviewing research under this Addendum shall sign and provide the requested information above.

C. Chair(s) of the IRB(s) that will Review DoD-DON Supported Research on behalf of the FWA Institution

Acting in an authorized capacity on behalf of this Institution's IRB(s) and with an understanding of the Institution's responsibilities under its FWA and this Addendum, I assure protections for human subjects as specified above. As Chair of the IRB(s), I shall provide oversight for all research approved by this IRB(s) and conducted under this Addendum.

Signature:



Date:

8/27/14

For IRB #(s): As applicable

Name: Reese Jones, MD Rank/Grade:

Institutional Title: Chair, Laurel Heights panel of the UCSF Committee on Human Research (IRB)

Telephone number: 415-476-7452 FAX number: 415-476-7690 Email address: reese.jones@ucsf.edu

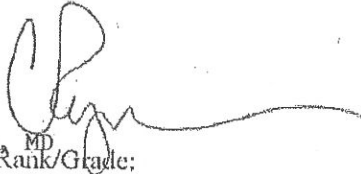
Mailing Address: 401 Parnassus Ave, Langley Porter Room A310, San Francisco, CA 94143

Note: Each IRB Chair of an IRB reviewing research under this Addendum shall sign and provide the requested information above.

C. Chair(s) of the IRB(s) that will Review DoD-DON Supported Research on behalf of the FWA Institution

Acting in an authorized capacity on behalf of this Institution's IRB(s) and with an understanding of the Institution's responsibilities under its FWA and this Addendum, I assure protections for human subjects as specified above. As Chair of the IRB(s), I shall provide oversight for all research approved by this IRB(s) and conducted under this Addendum.

Signature:



Date:

8/27/14

Name: Charles Ryan, MD
Rank/Grade:

For IRB #(s): As applicable

Institutional Title: Chair, Mount Zion panel of the UCSF Committee on Human Research (IRB)

Telephone number: FAX number: Email address:

Mailing Address: (415) 353-9279 (415) 353-7779 ryanc@medicine.ucsf.edu

1600 Divisadero St., Mount Zion Bldg A, Room A720, San Francisco, CA 94143

Note: Each IRB Chair of an IRB reviewing research under this Addendum shall sign and provide the requested information above.