



DEPARTMENT OF THE NAVY
OFFICE OF THE CHIEF OF NAVAL OPERATIONS
2000 NAVY PENTAGON
WASHINGTON DC 20350-2000

IN REPLY REFER TO:

3900
Ser M00R/09M00R236
27 Jul 09

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

DoD-Navy FWA Addendum: DoD N-A3060

Expiration Date: 24 June 2012

Institution: University of Southern California

The application for the Department of Defense - Navy Addendum to the Federalwide Assurance, FWA 00007099, held by the University of Southern California, is approved.

In accordance with the signed Addendum, the University of Southern California 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:

Department of the Navy
Office of Research Protections (M00R)
Bureau of Medicine and Surgery
2300 E Street, NW
Washington DC 20372-5300
Telephone: 202-762-0161, Fax: 202-762-0976
Email: human.research@med.navy.mil

A.M. Robinson, Jr.
A. M. ROBINSON, JR.
Vice Admiral, Medical Corps
United States Navy
Surgeon General of the Navy

Attachment:

University of Southern California DoD-Navy FWA Addendum application received 4 May 09

**Department of Defense
Human Research Protection Program**

**DEPARTMENT OF DEFENSE (DOD) ADDENDUM TO THE DEPARTMENT OF HEALTH
AND HUMAN SERVICE'S (DHHS) FEDERALWIDE ASSURANCE (FWA) FOR THE
PROTECTION OF HUMAN SUBJECTS**

This Addendum is for non-DoD Institutions that already have an FWA approved by DHHS and will be engaged in DoD-supported human subject research.

**Part 1
INSTITUTION INFORMATION**

A. Purpose of DoD Addendum

- New
 Renewal for DoD Addendum Number: DoD-N-A0060

B. Institution Information

Name: University of Southern California
DHHS FWA Number: FWA00007099
Description of the Institution: Academic Institution

C. Scope

This Addendum applies to all DoD-supported human research protocols performed by this institution, unless specified below.

Limitation of Scope (if applicable): _____

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
DOD REQUIREMENTS**

In addition to the requirements identified in the Institution's FWA, 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:

- 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 DoDD 3216.02
- Title 21 Code of Federal Regulations 50, 56, 312, and 812, Food and Drug Administration (FDA) Regulations
- DoD Directive (DoDD) 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"
- DoDD 3210.7, "Research Integrity and Misconduct"
- DoD Instruction (DoDI) 6200.02, "Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs"

Part 3 DOD COMPONENT REQUIREMENTS

The institution assures it shall also comply with DoD Component requirements for the research protocol(s) sponsored by that DoD Component. The requirements for each DoD Component are listed below. DoD Components may require that other research, not specifically identified by 32 CFR 219, also comply with the terms of this Addendum (32 CFR 219.101(d)).

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, 4 January 1991

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

National Geospatial Intelligence Agency

-

National Security Agency

-

Defense Intelligence Agency

-

Defense Threat Reduction Agency

-

Defense Advanced Research Projects Agency

-

United States Joint Forces Command

-

United States Special Operations Command

-

Part 4

INSTITUTION RESPONSIBILITIES

The complete list of requirements for compliance is provided above in Part 2, DoD Requirements; Part 3, DoD Component Requirements; and in the institution's FWA. A select list of responsibilities of the Institutional Official, IRB, and Investigators are identified below. This partial list is taken from the regulations and guidance listed in Parts 2 and 3. The institution should communicate with the DoD organization supporting the research to ensure the institution and their IRB are in compliance.

- Conduct initial and continuing research ethics education for personnel who are engaged in human subject research (e.g., who review, approve, oversee, or manage research)
- Document determination by a designated Institutional Official (other than investigators) whether research meets criteria for exemption
- Ensure new research and substantive scientific amendments to approved research shall undergo scientific review and that the review is considered by the IRB
- Ensure additional protections for military research subjects to minimize undue influence
- Explain to subjects any provisions for medical care for research-related injury
- Report unanticipated problems, adverse events, research-related injury, and suspensions or terminations of research
- Appoint a Medical Monitor when necessary
- Safeguard for research conducted with international populations

- Protect pregnant women, prisoners, and children
- Comply with DoD limitations on research where consent by legally authorized representatives is proposed
- Comply with DoD limitation on exceptions from informed consent (e.g., 10 USC 980, 45 CFR 46, and 21 CFR 50)
- Comply with limitations on dual compensation for U. S. military personnel
- Follow DoD requirements for additional review for DoD-sponsored survey research or survey research within DoD
- Address and report allegations of non-compliance with human research protections
- Address and report allegations of research misconduct
- Follow procedures for addressing financial and other conflicts of interest
- Prohibit research with prisoners of war (POW)
- Comply with all provisions for research with human subjects using investigational test articles (drugs, device, and biologics)
- Follow recordkeeping requirements
- Support oversight by the sponsoring DoD Component (which may include DoD Component review of the research and site visits)

Part 5
DESIGNATION OF IRB(S) THAT WILL REVIEW DOD-SUPPORTED RESEARCH

All of the IRBs supporting the institution do not need to be listed in Tables 1 and 2. List only those IRBs that will review DoD-supported research.

A. IRB(s) that are Part of this Institution

In Table 1, identify each IRB that is organizationally part of this institution and can review DoD-supported research under this Addendum to the FWA (the IRBs should also be listed on the FWA). For each IRB listed in Table 1, the IRB Chair must sign this Addendum in Part 6. When requested by the DoD-sponsor, attach the membership list for each IRB listed (in accordance with 45 CFR 46); see Table 3 for an example.

Table 1. IRB(s) within the Institution –

IRB Name or Number	DHHS IRB Registration Number (8 digits)
1. University of Southern California # 1 – Socio-behavioral	IRB00000387
2. University of Southern California (LAC +USC) IRB # 1	IRB00000484
3. University of Southern California (LAC +USC) IRB # 2	IRB00002880
4. University of Southern California (LAC +USC) IRB # 3	IRB00002881

B. IRB(s) that are not Part of this Institution

In Table 2, identify each IRB that is not associated with this institution and can review DoD-supported research under this Addendum to the FWA. For each IRB listed in Table 2, attach the DoD Institutional Agreement for IRB Review (or an equivalent agreement). When requested by the DoD-sponsor, attach the membership list for each IRB listed (in accordance with 45 CFR 46); see Table 3 for an example.

Table 2. IRB(s) not part of this Institution

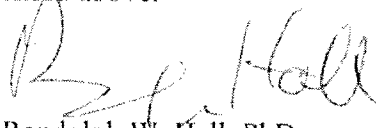
IRB Name or Number	DHHS IRB Registration Number (8 digits)*	Name of the Institution Providing the IRB	DoD Assurance Number of the Institution*	DHHS FWA Number of the Institution*
1.				
2.				
3.				
4.				
5.				
6.				

* If applicable.

**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 its FWA and this Addendum, I assure protections for human subjects as specified above.

Signature: 

Date: 4/23/09

Name: Randolph W. Hall, PhD

Institutional Title: Vice Provost of Research Advancement – Office of the Vice Provost

Telephone number: 213-740-6709

FAX number: 213-740-8919

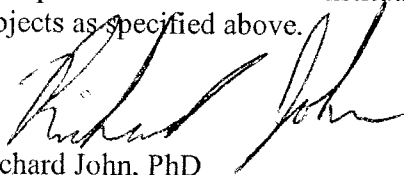
Mailing Address: 3720 South Flower 3rd Floor (CUB) Room 325(A) Los Angeles, CA 90089-0706

Email address: rwhall@usc.edu

B. Chair(s) of the IRB(s) that are part of the Institution and listed in Table 1

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

Signature:



Date: 1 May 2009

Name: Richard John, PhD

Telephone number: 213-740-4011

Institutional Title: Associate Professor of Psychology

Institution: University of Southern California – University Park IRB (UPIRB)

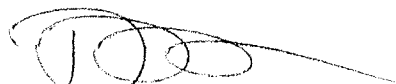
FAX number: 213-821-5276

Email address: richardj@usc.edu

Name(s) or Number of IRB: IRB00000387

Mailing Address (if different from the Institutional Official above): 837 Downey Way STO224A
Los Angeles, CA 90089-1146

Signature:



Date: April 13, 2009

Name: Darcy Spicer, MD

Telephone number: 323-223-2340

Institutional Title: Associate Professor of Clinical Medicine - Oncology

Institution: University of Southern California – Health Sciences IRB (HSIRB)

FAX number: 323-224-8389

Email address: dspicer@usc.edu

Name(s) or Number of IRB: IRB00000484, IRB00002880, IRB00002881

Mailing Address (if different from the Institutional Official above): 2020 Zonal Avenue, Room
425 Los Angeles, CA 90033

Note: If there are multiple IRBs listed in Table 1, each Chair should sign this Addendum and provide the information in this section. If a Chair presides over multiple IRBs listed in Table 1, provide the name and number of each IRB in this section.

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

Name: Kristin J. Craun, MPH, CIP

Telephone number: 213-821-5272

FAX number: 213-821-5276

Institutional Title: Director of UPIRB

Email address: kristija@usc.edu

Mailing Address: 837 Downey Way STO 224A Los Angeles, CA 90089-1146
(if different from the Institutional Official above):