



DEPARTMENT OF THE NAVY

BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
WASHINGTON DC 20372-7300

IN REPLY REFER TO

3900
Ser M00R/09UM00R105
14 Jan 09

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

DoD-Navy FWA Addendum: DoD N-A3099

Expiration Date: 22 December 2011


Institution: Columbia University

The application for a Department of Defense - Navy Addendum to the Federalwide Assurance, FWA 00003831 held by Columbia University, is approved.

Columbia University agrees 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.
Vice Admiral, Medical Corps
United States Navy
Surgeon General of the Navy

Attachment:

Columbia University DoD-Navy FWA Addendum Application received 19 December 08

**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 FEDERALWIDE
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:

- New
- Renewal for DoD-DON Addendum Number: A0099
- Update for DoD-DON Addendum Number:

B. Institution Information:

Name: The Trustees of the Columbia University in the City of New York
Mailing Address: New York, NY
Department of Health and Human Services (DHHS) FWA Number: FWA00003831

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 Navy Surgeon General 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 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"
- DoDD 6200.2, "Use of Investigational New Drugs in Force Health Protection"

Part 3
DOD COMPONENT SPECIFIC REQUIREMENTS

Department of the Army

Department of the Air Force

Department of the Navy

SECNAVINST 3900.39D of 6 November 2006

SECNAVINST 5720.44B of 1 November 2005

SECNAV M-5210.1 of 1 December 2005

OPNAVINST 5300.8B of 23 April 1997

National Geospatial Intelligence Agency

National Security Agency

Defense Intelligence Agency

Defense Threat Reduction Agency

Defense Advanced Research Projects Agency

United States Joint Forces Command

Office of the Secretary of Defense (Personnel and Readiness)

Special Operations Command

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, the IRB Chair must sign the Institutional Agreement in Part 6.

Table 1. Institutional IRB(s)

Institutional Name or Number of IRB	DHHS IRB Registration Number
1. Columbia University, Morningside IRB	IRB00006799
2.	
3.	
4.	
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 is 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. None				
2.				
3.				
4.				
5.				
6.				

**Part 6
INSTITUTIONAL AGREEMENT**

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: 

Date: 12-18-2008

Name: David Hirsh, Ph.D.

Rank/Grade: N/A

Telephone number: 212-854-1656

Institutional Title: Executive Vice President for Research FAX number: 212-854-1696

Mailing Address: 535 W. 116th Street, Mail Code 4310 Email address: dh1@columbia.edu
New York, NY 10027

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: 12-18-2008

Name: Andrew Nathan, Ph.D.

Rank/Grade: N/A

Telephone number: 212-851-7040

Institutional Title: Chair, Columbia University IRB

FAX number: 212-851-7044

Mailing Address: 637 W. 125th Street, Room 212email address: ain1@columbia.edu

Mail Code - MC8602

New York, NY 10027

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

Primary Contact - Human Research Protection of the FWA Institution

Signature: 

Date: 12/19/08

Name: George Gasparis

Rank/Grade: N/A

Telephone number: 212-305-3257

Institutional Title: Asst. V.P./ Sr. Asst. Dean for Research Ethics FAX number: 212-305-1316

Mailing Address: 722 W. 168th Street, Room 426Email address: gg2120@columbia.edu

New York, NY 10032