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: 20 April 2017

Institution: Columbia University

The application for the Department of Defense - Navy Addendum to the Federalwide Assurance, FWA00003831, held by Columbia University, is approved.

In accordance with the signed Addendum, Columbia University 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
Office of Research Protections (M00RP)
7700 Arlington Blvd, Ste 5121
Falls Church, VA 22042-5121
Telephone: 703-681-9629, Fax: 703-681-2597
Email: human.research@med.navy.mil

M. L. NATHAN
Vice Admiral, Medical Corps
United States Navy
Surgeon General of the Navy

Attachment:
Columbia University DoD-Navy FWA Addendum application did 25 May 2012
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
[X] Renewal for DoD-DON Addendum Number: DOD-NA3099
[ ] Update for DoD-DON Addendum Number: __________
DoD-DON Addendum Expiration Date: December 22, 2011

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: FWA00063831
FWA Expiration Date: April 20, 2017

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 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, 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

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, prisonners, 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>
<thead>
<tr>
<th>Institutional Name or Number of IRB</th>
<th>DHHS IRB Registration Number</th>
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<tbody>
<tr>
<td>1. CUMC IRB #1</td>
<td>IRB00000461</td>
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<td>2. CUMC IRB #2</td>
<td>IRB000002272</td>
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<td>3. CUMC IRB #3</td>
<td>IRB00003506</td>
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<td>4. CUMC IRB #4</td>
<td>IRB00006882</td>
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<td>5. CUMC IRB #6</td>
<td>IRB00008612</td>
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<td>6. CU IRB Morningside</td>
<td>IRB00006799</td>
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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>
<thead>
<tr>
<th>Name of Institution</th>
<th>DoD Assurance Number</th>
<th>Name or Number of IRB</th>
<th>DHHS/FWA Number</th>
<th>DHHS IRB Registration Number</th>
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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: [Signature]

Date: 05-17-12

Name: G. Michael Purdy, Ph.D.
Rank/Grade: [Rank/Grade]
Institutional Title: Executive Vice President for Research
Mailing Address: 313 Low Library
         Columbia University
         New York, NY 10027

Telephone number: 212.854.1656
FAX number: 212.854.1690
Email address: gmp63@columbia.edu

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 it’s 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: [Signature]

Date: 5/21/12

Name: Marilyn Morris, M.D.
Rank/Grade: [Rank/Grade]
Institutional Title: Assoc. Professor
Mailing Address: BHN 10th floor, Room 24
         630 W. 168th St., NY, NY 10032

For IRB #(s): CUMC IRB #1
Telephone number: 212.305.8438
FAX number: 212.342.2293
Email address: mmorris13@columbia.edu

Signature: [Signature]

Date: 5/7/12

Name: Elaine Larson, Ph.D
Rank/Grade: [Rank/Grade]
Institutional Title: Professor
Mailing Address: 617 W. 168th St., Room 330
         NY, NY 10032

For IRB #(#s): CUMC IRBs 2 & 6
Telephone number: 212.305.0723
FAX number: 212.305.0722
Email address: ehl23@columbia.edu
Signature:  
Name: Neil Schluger, M.D.  
Rank/Grade:  
Institutional Title: Professor  
Mailing Address: 622 W. 168th St. 
PH8 East Room 101, NY, NY 10032 
Date:  
For IRB #(s): CUMC IRB #3 
Telephone number: 212.305.9817 
FAX number: 212.342.5272 
Email address: nes11@columbia.edu 

Signature:  
Name: Balazs Halmos, M.D.  
Rank/Grade:  
Institutional Title: Associate Clinical Professor 
Mailing Address: 161 Ft. Washington, 9th Floor NY, NY 10032 
Date:  
For IRB #(s): CUMC IRB #4 
Telephone number: 212.305.6762 
FAX number: 212.305.5376 
Email address: bh2376@columbia.edu 

Signature:  
Name: Andrew Nathan, Ph.D.  
Rank/Grade:  
Institutional Title: Professor 
Mailing Address: International Affairs Building 420 W. 118th St. Room 214 
New York, NY 10027 
Date:  
For IRB #(s): CU-MS 
Telephone number: 212.854.6909 
FAX number: 212.749.1497 
Email address: an211@columbia.edu 

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

Primary Contact - Human Research Protection of the FWA Institution
Signature:  
Name: Alan Teller  
Rank/Grade:  
Institutional Title: Assistant Director of IRB Operations 
Mailing Address: 722 W. 168th Street, R426 
New York, NY 10032 
Date:  
Telephone number: 212.342.0634 
FAX number: 212.305.1316 
Email address: at2052@columbia.edu