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

DoD-Navy FWA Addendum: DoD N-A3267

Expiration Date: 2 February 2017

Institution: Columbia University Medical Center

The application for the Department of Defense - Navy Addendum to the Federalwide Assurance, FWA00002636, held by Columbia University Medical Center, is approved.

In accordance with the signed Addendum, Columbia University Medical Center 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, Suite 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 Medical Center DoD-Navy FWA Addendum application dtd 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: DoD-NA3267

[ X ] New
[ ] Renewal for DoD-DON Addendum Number: 
[ ] Update for DoD-DON Addendum Number: 
DoD-DON Addendum Expiration Date: 

B. Institution Information:

Name: Columbia University Medical Center (CUMC)
Mailing Address: 630 W. 168th Street, New York, NY 10032
Department of Health and Human Services (DHHS) FWA Number: FWA00002636
FWA Expiration Date: February 2, 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 assurs 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, 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

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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, 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)

<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>IRB00002973</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 2. DoD or non-DoD IRB(s) not Part of this Institution

<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: ___________________________ Date: 5/21/12

Name: Steven Shea, M.D.
Rank/Grade:
Institutional Title: Senior Vice Dean
Mailing Address: College of Physicians & Surgeons
630 W. 168th Street, 2-401
New York, NY 10032

Telephone number: 212.305.8707
FAX number: 212.305.3545
Email address: ss35@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: ___________________________ Date: 5/21/12

Name: Marilyn Morris, M.D.
Rank/Grade:
Institutional Title: Assoc. Professor
Mailing Address: RHIN 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: mcm2113@columbia.edu

Signature: ___________________________ Date: 5/17/12

Name: Elaine Larson, Ph.D.
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: ell23@columbia.edu

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Signature: Neil Schluger, M.D.
Name: Neil Schluger, M.D.
Rank/Grade: 
Institutional Title: Professor
Mailing Address: 622 W. 168th St.,
PH8 East Room 101, NY, NY 10032
Date: 5/16/12
For IRB #(s): CUMC IRB #3
Telephone number: 212.305.9817
FAX number: 212.342.5272
Email address: ns311@columbia.edu

Signature: Balazs Halmos, M.D.
Name: Balazs Halmos, M.D.
Rank/Grade: 
Institutional Title: Associate Clinical Professor
Mailing Address: 161 Ft. Washington, 9th Floor
NY, NY 10032
Date: 5/18/12
For IRB #(s): CUMC IRB #4
Telephone number: 212.305.6762
FAX number: 212.305.5576
Email address: bh2376@columbia.edu

Signature: Andrew Nathan, Ph.D.
Name: Andrew Nathan, Ph.D.
Rank/Grade: 
Institutional Title: Professor
Mailing Address: International Affairs Building
420 W. 118th St., Room 914
New York, NY 10027
Date: May 25, 2012
For IRB #(s): CU-MSS
Telephone number: 212.854.6909
FAX number: 212.749.1497
Email address: ain1@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: Alan Teller
Name: Alan Teller
Rank/Grade: Assistant Director of IRB Operations
Institutional Title: Assistant Director of IRB Operations
Mailing Address: 722 W. 168th Street, R426
New York, NY 10032
Date: 5/16/12
Telephone number: 212.342.0034
FAX number: 212.305.1316
Email address: at2059@columbia.edu