



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 M00RP/11UM00RP316  
12 Dec 2011

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

**DoD-Navy FWA Addendum:** DoD N-A3063

**Expiration Date:** 13 June 2014

**Institution:** University of Michigan

The application for the Department of Defense - Navy Addendum to the Federalwide Assurance, FWA00004969, held by the University of Michigan, is approved.

In accordance with the signed Addendum, the University of Michigan 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 (M00RP)  
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](mailto:human.research@med.navy.mil)

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

Attachment:

University of Michigan DoD-Navy FWA Addendum application dtd 8 Nov 2011

**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: DoD N-A0063  
 Update for DoD-DON Addendum Number:

**B. Institution Information:**

Name: University of Michigan  
Mailing Address: 4080 Fleming Building, 503 Thompson St, Ann Arbor, MI 48109  
Department of Health and Human Services (DHHS) FWA Number: FWA00004969  
FWA Expiration Date: June 13, 2014

**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

- 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, 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)**

<b>Institutional Name or Number of IRB</b>	<b>DHHS IRB Registration Number</b>
U of Michigan IRBMED A-1	IRB00000244
U of Michigan IRBMED A-2	IRB00001996
U of Michigan IRBMED B-1	IRB00001999
U of Michigan IRBMED B-2	IRB00001995
U of Michigan IRBMED C-1	IRB00005467
U of Michigan IRB Health	IRB00000245
U of Michigan IRB Behavioral Sciences	IRB00000246
U of Michigan Dearborn	IRB00000247
U of Michigan Flint	IRB00000248

**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**

<b>Name of Institution</b>	<b>DoD Assurance Number</b>	<b>Name or Number of IRB</b>	<b>DHHS/FWA Number</b>	<b>DHHS IRB Registration Number</b>
1.				
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: 11/5/11

Name: Stephen R. Forrest, PhD  
Institutional Title: Vice President for Research  
Mailing Address: 4080 Fleming Building,  
503 Thompson St., Ann Arbor, MI 48109

Telephone number: 734 764-1185  
FAX number: 734 763-0085

Email address: [stevefor@umich.edu](mailto:stevefor@umich.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 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: 

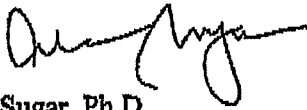
Date: 11/4/11

Name: Michael Geisser, Ph.D.  
Institutional Title: Co-Chair, IRBMed  
Mailing Address: IRBMED  
2800 Plymouth Rd.  
Building 200, Room 2086  
Ann Arbor, MI 48109-2800  
Telephone number: 734 763-4768  
FAX number: 734 763-1234  
Email address: mgeisser@umich.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 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:



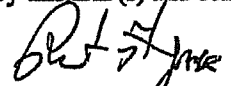
Date:

11/6/2011

Name: Alan Sugar, Ph.D.  
Institutional Title: Co-Chair, IRBMed  
Mailing Address: IRBMED  
2300 Plymouth Rd.  
Building 200, Room 2086  
Ann Arbor, MI 48109-2800  
Telephone number: 734 763-4768  
FAX number: 734 763-1234  
Email address: asugar@umich.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 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: 11/3/11

Name: Robert Hymes, Ph.D.  
Institutional Title: Chair, IRB Dearborn  
Mailing Address: 1055 Administration Building  
4901 Evergreen Road, Dearborn, MI 48128-2406  
Telephone number: 313 593-5468  
FAX number: 313 593-0526  
Email address: rhymes@umich.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 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: *November 8, 2011*

Name: Richard Redman

Institutional Title: Chair, IRB Health Sciences and Behavioral Sciences

Mailing Address: 540 East Liberty Street, Suite 202, Ann Arbor, MI 48104-2210

Telephone number: 734 936-0933

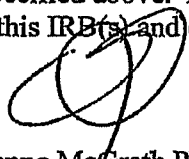
FAX number: 734 998-9171

Email address: rwr@umich.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 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:

11/3/11

Name: Marianne McGrath Ph.D.  
Institutional Title: Chair, IRB Flint  
Mailing Address: 530 French Hall  
303 East Kearsley Street, Flint MI 48502-1950  
Telephone number: 801 766-6791  
FAX number: 3810 766-6791  
Email address: mmcgrath@umich.edu

**Primary Contact - Human Research Protection of the FWA Institution**

Signature: 

Date: 4/8/11

Lois Brako, Ph.D.

Institutional Title: Assistant Vice President for Research –  
Regulatory and Compliance Oversight

Mailing Address: Office of the Vice President for Research  
University of Michigan

4048 Fleming Bldg., 503 Thompson Street

Ann Arbor, MI 48109-1340

Telephone number: 734-615-8936

FAX number: 734-763-0085

Email: [lbrako@umich.edu](mailto:lbrako@umich.edu)