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: 03 January 2019

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:

Bureau of Medicine and Surgery
Skyline Detachment
Department of the Navy
Human Research Protection Program (M00RPH)
7700 Arlington Blvd., Suite 5160
Falls Church, VA 22042-5160
Telephone: 703-681-9629, Fax: 703-681-2597
Email: human.research@med.navy.mil

W. M. DENISTON
Captain, Medical Service Corps
United States Navy
Director, Department of the Navy
Human Research Protection Program
By Direction of the Surgeon General of the Navy

Attachment:
University of Michigan DoD-Navy FWA Addendum application dtd 11 Jun 2014
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 N-A3063

[ ] Update for DoD-DON Addendum Number: __________________________
  DoD-DON Addendum Expiration Date: ____________

B. Institution Information:

Name: University of Michigan  
Mailing Address: Office of Research, 4080 Fleming Building;  
503 Thompson Street, Ann Arbor, MI 48109  
Department of Health and Human Services (DHHS) FWA Number: 00004969
FWA Expiration Date: January 3, 2019

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 DoD Component Designated Official 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, 19 October 2009

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

DoD N Addendum to FWA_June2014 (1) (1).doc
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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 biologies)
- 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. U of Michigan IRBMED A-1 #1</td>
<td>IRB00000244</td>
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<td>2. U of Michigan IRB #2 - Hlth</td>
<td>IRB00000245</td>
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<td>3. U of Michigan IRB #3 - Behavioral Science</td>
<td>IRB00000246</td>
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<td>4. U of Michigan Dearborn IRB #4</td>
<td>IRB00000247</td>
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<td>5. U of Michigan Flint IRB #5</td>
<td>IRB00000248</td>
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<td>6. U of Michigan IRBMED B-2 #6</td>
<td>IRB00001995</td>
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<td>7. U of Michigan IRBMED A-2 #7</td>
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<td>8. U of Michigan IRBMED B-1 #8</td>
<td>IRB00001999</td>
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<td>9. U of Michigan IRBMED C-1 #9</td>
<td>IRB00005467</td>
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</tbody>
</table>

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: 6/9/2014

Name: S. Jack Hu
Rank/Grade: Ph.D.
Institutional Title: Interim Vice President for Research
Mailing Address: 4080 Fleming Building; 503 Thompson Street; Ann Arbor, MI 48109
Email address: jackhu@umich.edu

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

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: [Signature] Date: 

Name: Alan Sugar
Rank/Grade: M.D.
Institutional Title: Interim IRB Co-Chair; Professor
Mailing Address: IRBMED; 2800 Plymouth Road; Bldg 200 Rm 2086; Ann Arbor, MI 48109
Email address: asugar@umich.edu

For IRB #(s): IRB00000244
IRB00001995
Telephone number: 734-763-4768
FAX number: 734-763-9603

*NOTE: All signature block information MUST be typed*
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: ___________________________

Name: ___________________________ Telephone number: ___________________________
Rank/Grade: ___________________________ FAX number: ___________________________
Institutional Title: ___________________________ Email address: ___________________________
Mailing Address: ___________________________

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: 1/21/14

Name: Alan Sugar MD
Rank/Grade: ___________________________
Institutional Title: Professor, Ophthalmology
Mailing Address: 1000 Wall St
Ann Arbor, MI 48105

For IRB #(s): IRB00000244, 00001995
Telephone number: 734-763-4768
FAX number: ___________________________
Email address: asugar@umich.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: ___________________________ Date: ___________________________

Name: ___________________________
Rank/Grade: ___________________________
Institutional Title: ___________________________
Telephone number: ___________________________
FAX number: ___________________________

DoD N Addendum to FWA_01 Feb 2013.doc
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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:  
Name:  
Rank/Grade:  
Institutional Title:  
Mailing Address:  

Date:  
Telephone number:  
FAX number:  
Email address:  

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:  
Name: Robert Hymes, Ph.D.  
Rank/Grade:  
Institutional Title: Associate Professor  
Mailing Address: Dept. of Behavioral Sciences University of Michigan-Dearborn

Date:  
For IRB #(s): IRB00000247  
Telephone number: (313) 593-5163  
FAX number:  
Email address: rhymes@umich.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:  
Rank/Grade:  
Institutional Title:  
Mailing Address:  

Date:  
Telephone number:  
FAX number:  
Email address:  

DoD N Addendum to FWA_01 Feb 2013.doc

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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:  
[Signature]

Date:  
6/29/14

Name: James A. Ashton-Miller  
Rank/Grade: Ph.D.  
Institutional Title: Associate Vice President for Research  
Mailing Address: 4080 Fleming Building; 503 Thompson Street; Ann Arbor, MI 49109  
Telephone number: 734-763-1289  
FAX number: 734-763-0085  
Email address: jaam@umich.edu
Signature: Michael Geisser  
Date: 6/16/14

Name: Michael Geisser  
For IRB #(#): IRB00001996  
IRB00001999  
IRB00005467  
Rank/Grade: Ph.D.  
Institutional Title: IRB Chairperson; Assoc. Professor  
Telephone number: 734-763-4768  
FAX number: 734-763-9603  
Mailing Address: IRBMED; 2800 Plymouth Road; Bldg 200 Rm 2086; Ann Arbor, MI 48109  
Email address: mgeisser@umich.edu

Signature:  
Date:

Name: Thad Polk  
For IRB #(#): IRB00000245  
IRB00000246  
Rank/Grade: Ph.D.  
Institutional Title: IRB Chairperson; Associate Professor  
Telephone number: 734-763-1289  
FAX number: 734-763-0085  
Mailing Address: Human Subjects Protection Office; 40700 Fleming Building;  
503 Thompson Street; Ann Arbor, MI 48109  
Email address: tpolk@umich.edu

Signature:  
Date:

Name: Robert Hynes  
For IRB #(#): IRB00000247  
Rank/Grade: Ph.D.  
Institutional Title: IRB Chairperson; Professor  
Telephone number: 313-593-5520  
FAX number: n/a  
Mailing Address: Department of Behavioral Sciences; 4012 CASL Building;  
4901 Evergreen Road; Dearborn, MI 48128  
Email address: rhynes@umich.edu

Signature:  
Date: 6/11/14

Name: Mariann McGrath  
For IRB #(#): IRB00000248  
Rank/Grade: Ph.D.  
Institutional Title: IRB Chairperson; Professor  
Telephone number: 810-762-3424  
FAX number: n/a  
Mailing Address: 411 W. Murchie Science Bldg; University of Michigan-Flint; Flint, MI 48502  
Email address: mmcgrath@umich.edu

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*NOTE: All signature block information MUST be typed*
Signature:

Name: Michael Geisser

Rank/Grade: Ph.D.
Institutional Title: IRB Chairperson; Assoc. Professor
Mailing Address: IRBMED; 2800 Plymouth Road; Bldg 200 Rm 2086; Ann Arbor, MI 48109
Email address: mgeisser@umich.edu

Date: For IRB #(s): IRB00001996
IRB00001999
IRB00005467
Telephone number: 734-763-4768
FAX number: 734-763-9603

Signature:

Name: Thad A. Polk

Rank/Grade: Ph.D.
Institutional Title: IRB Chairperson; Professor
Mailing Address: IRB-HSBS, 540 E. Liberty St. #202
Ann Arbor, MI 48104
Email address: tpolk@umich.edu

Date: 6/11/2014
For IRB #(s): IRB00000245
IRB00000246
Telephone number: 734-936-0933
FAX number: 734-998-9171

Signature:

Name: Robert Hymes

Rank/Grade: Ph.D.
Institutional Title: IRB Chairperson; Professor
Mailing Address: Department of Behavioral Sciences; 4012 CASL Building;
4901 Evergreen Road; Dearborn, MI 48128
Email address: rhymes@umich.edu

Date:
For IRB #(s): IRB00000247
Telephone number: 313-593-5520
FAX number: n/a

Signature:

Name: Marianne McGrath

Rank/Grade: Ph.D.
Institutional Title: IRB Chairperson; Professor
Mailing Address: 411 W. Murchie Science Bldg; University of Michigan- Flint; Flint, MI 48502
Email address: mmcgrath@umich.edu

Date:
For IRB #(s): IRB0000248
Telephone number: 810-762-3424
FAX number: n/a

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