



DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
WASHINGTON DC 20372-5300

IN REPLY REFER TO

3900
Ser M00R/07M00R221
AUG - 7 2007

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

DoD-Navy FWA Addendum: DoD N-A0046

Expiration Date: 10 January 2010

Institution: University of Washington

RECEIVED
Human Subjects Division

AUG 20 2007

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The application for a Department of Defense - Department of the Navy Addendum to the Federalwide Assurance, FWA 00006878 held by the University of Washington, is approved.

The University of Washington agrees to abide by Department of Defense – Department of Navy regulations and policies for the protection of human research participants when conducting, reviewing, approving, overseeing, supporting or managing Department of the 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

D. C. ARTHUR
Vice Admiral, Medical Corps
United States Navy
DON Assurance Approving Official

Attachment:
University of Washington DoD-Navy FWA Addendum Application dated 10 July 07

AUG 20 2007

Department of the Navy
Human Research Protection Program

UW

**DoD-Navy Addendum to Federalwide Assurance of Protection for Human Subjects
For Institutions Conducting or Collaborating in DON-supported Human Subject Research**

New Addendum Addendum Renewal Addendum Update

Institution Name: **UNIVERSITY OF WASHINGTON**

Address: **3935 University Way NE, Seattle, WA 98105-6613**

Federalwide Assurance #: **FWA00006878** FWA Expiration Date: **01/10/2010**

FWA IRB(s) #: **IRB00000241; IRB00000242; IRB00000243; IRB00000727; IRB00002532;
IRB00004442; IRB00005647**

Part 1

Department of Defense (DoD) and Department of the Navy (DON) Regulations and Guidance

This institution assures it will comply with the following regulations and guidance when conducting, reviewing, approving, overseeing, supporting, or managing DON-supported research with human subjects:

- The Belmont Report
- 32 Code of Federal Regulations Part 219 (32 CFR 219), Department of Defense Regulations, "Protection of Human Subjects"
- 45 Code of Federal Regulations Part 46, (45 CFR 46) Department of Health and Human Services Regulations, "Protection of Human Subjects"
- Department of Defense (DoD) Directives 3216.2, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-supported Research"
- Secretary of the Navy Instruction 3900.39D, "Human Research Protection Program"
- Title 21 Code of Federal Regulations 50, 56, 312, 600, 812, Food and Drug Administration (FDA) regulations
- DoDI 3210.7, "Research Integrity and Misconduct"
- DoDD 6200.2, "Use of Investigational New Drugs in Force Health Protection"
- Other relevant DON instructions or policies and procedures.

These regulations and guidance address such matters as:

- Initial and continuing research ethics training for all personnel who conduct, review, approve, oversee, support, or manage human subject research
- Written determination by a designated official (other than investigators) whether research meets criteria for exemption
- New research and substantive amendments to approved research must undergo scientific approval 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 Medical Monitor
- Additional safeguards for research conducted with international populations
- Additional protections for pregnant women, prisoners, and children (Subparts B, C, and D of 45 CFR 46)
- Limitations on research where consent by legally authorized representatives is proposed
- Limitation on exceptions from informed consent in emergency research
- Limitations on compensation for U. S. military personnel
- U. S. Navy-wide survey research requires additional review
- 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)
- Oversight by the DON HRPP through headquarters-level review of research protocols (including relevant IRB meeting minutes) after local institutional approval and site visits of the institution's HRPP

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Part 2
Institutional Affirmation: Institution with its own IRB(s)

The undersigned are aware of the additional DoD and DON requirements, have ready access to the above regulations and guidance, and ensure that the institution complies with the requirements.

Official Legally Authorized to Represent the FWA Institution

Signature: Jeff M. Cheek Date: 7/10/07

Name: **JEFF-CHEEK, PH.D.**

Institutional Title: **ASSOCIATE VICE PROVOST FOR RESEARCH
COMPLIANCE AND OPERATIONS**

Address: **UNIVERSITY OF WASHINGTON, OFFICE OF RESEARCH,
G-80 GERBERDING HALL, BOX 355752, SEATTLE, WA
98195-1202**

Telephone number: **206 616-9496**

FAX: **206-685-9210**

Email address: **jcheek@u.washington.edu**

Primary Contact - Human Research Protections

Signature: Karen E. Moe Date: 7/9/07

Name: **KAREN MOE, PH.D.**

Institutional Title: **EXECUTIVE DIRECTOR, HUMAN SUBJECTS
DIVISION**

Address: **3935 UNIVERSITY WAY NE, SEATTLE, WA 98105-6613**

Telephone number: **206-543-0098**

FAX: **206-543-9218**

Email address: **kemoe@u.washington.edu**

IRB Chair(s)

Signature: Edmund Chaney Date: 5/8/07

Name: **Edmund Chaney**

Institutional Title: **Chair, IRB Committee C**

Address: **3935 University Way NE, Seattle, WA 98105-6613**

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FAX: **206-543-9218**

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