



DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON DC

MAR 06 2009

MEMORANDUM FOR THE UNIVERSITY OF WASHINGTON
ATTN: JEFFREY M. CHEEK, ASSOCIATE VICE PROVOST FOR
RESEARCH COMPLIANCE & OPERATIONS

FROM: HQ USAF/SGRC
Office of the Surgeon General
5201 Leesburg Pike, Suite 1501B
Falls Church, VA 22041

SUBJECT: Approval of Air Force (AF) Issued DoD Addendum to the Department of Health and
Human Service's Federalwide Assurance (FWA) Number 00006878

References: (a) 32 CFR 219, Protection of Human Subjects
(b) 10 USC 980, Limitation on Use of Humans as Experimental Subjects
(c) AFI 40-402, Protection of Human Subjects in Research
(d) DoDD 3216.02, Protection of Human Subjects and Adherence to Ethical
Standards in DoD-Supported Research

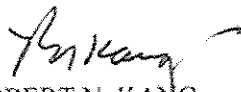
On behalf of the AF Surgeon General, I have approved your DoD Addendum to the FWA referenced
above. Following are your institution's DoD Addendum number and a description of research covered.

<u>DoD Number</u>	<u>Research Covered</u>
F50320	FSG20090004H "All research with human subjects performed by the University of Washington and conducted or supported by the Air Force".

You may submit to my office requests to add protocols to this Addendum after they have been approved
by the Institutional Review Board (IRB) identified in your Addendum. Coverage will apply as of the date
of the approval letter issued by our office specifically identifying the protocol.

In order to comply with this Addendum, you must provide to my office a copy of all continuing
review reports submitted to the IRB in addition to the reports required by the above References. Please
maintain a copy of the attached approved Addendum with your research records.

Thank you for your support in this matter. Please do not hesitate to contact me at 703-681-6277, telefax
703-681-6913, or robert.kang@pentagon.af.mil.


ROBERT N. KANG
Lt Col, USAF, BSC
Chief, Research Oversight & Compliance Division
Office of the Surgeon General

Attachment: DoD # F50320



Human Subjects Division
Office of Research
University of Washington
Box 359470
Seattle, WA 98105-9470
206-543-0098

**Department of Defense
Human Research Protection Program**

**AIR FORCE ISSUED DEPARTMENT OF DEFENSE (DOD) ADDENDUM
TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICE'S (DHHS)
FEDERALWIDE ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS**

This Addendum is for non-DoD Institutions that already have an FWA approved by DHHS and will be engaged in DoD-supported human subject research.

**Part 1
INSTITUTION INFORMATION**

A. Purpose of DoD Addendum

- New
 Renewal for DoD Addendum Number:

B. Institution Information

Name: University of Washington, including University of Washington, UW Medicine, Harborview Medical Center, Seattle Cancer Care Alliance, UW Physicians

DHHS FWA Number: FWA00006878

Description of the Institution: The University of Washington is a large, public, research university and academic medical center. All types of research are performed, covering a broad area of (1) topics/foci (e.g., biomedical, social/behavioral), (2) methodology and approach (e.g., clinical trials, field research, community participatory research, questionnaires, interventions), and (3) subject populations (patients; healthy volunteers; minors; prisoners; decisionally-impaired; other protected and vulnerable populations). The research is funded by government grants and contracts; commercial entities; private foundations and non-profits; gifts and donations; and Washington State funds.

C. Scope

This Addendum applies to all DoD-supported human research protocols performed by this institution, unless specified below.

Limitation of Scope (if applicable): Not applicable

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 DOD REQUIREMENTS

In addition to the requirements identified in the Institution's FWA, 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:

- 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"
- DoD Instruction (DoDI) 6200.02, "Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs"

Part 3 DOD COMPONENT REQUIREMENTS

The institution assures it shall also comply with DoD Component requirements for the research protocol(s) sponsored by that DoD Component. The requirements for each DoD Component are listed below. DoD Components may require that other research, not specifically identified by 32 CFR 219, also comply with the terms of this Addendum (32 CFR 219.101(d)).

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

Part 4 INSTITUTION RESPONSIBILITIES

The complete list of requirements for compliance is provided above in Part 2, DoD Requirements; Part 3, DoD Component Requirements; and in the institution's FWA. A select list of responsibilities of the Institutional Official, IRB, and Investigators are identified below. This partial list is taken from the regulations and guidance listed in Parts 2 and 3. The institution should communicate with the DoD organization supporting the research to ensure the institution and their IRB are in compliance.

- Conduct initial and continuing research ethics education for personnel who are engaged in human subject research (e.g., who review, approve, oversee, or manage research)
- Document determination by a designated Institutional Official (other than investigators) whether research meets criteria for exemption
- Ensure new research and substantive scientific amendments to approved research shall undergo scientific review and that the review is considered by the IRB
- Ensure additional protections for military research subjects to minimize undue influence
- Explain to subjects any provisions for medical care for research-related injury
- Report unanticipated problems, adverse events, research-related injury, and suspensions or terminations of research
- Appoint a Medical Monitor when necessary
- Safeguard for research conducted with international populations
- Protect pregnant women, prisoners, and children
- Comply with DoD limitations on research where consent by legally authorized representatives is proposed
- Comply with DoD limitation on exceptions from informed consent (e.g., 10 USC 980, 45 CFR 46, and 21 CFR 50)
- Comply with limitations on dual compensation for U. S. military personnel
- Follow DoD requirements for additional review for DoD-sponsored survey research or survey research within DoD
- Address and report allegations of non-compliance with human research protections
- Address and report allegations of research misconduct
- Follow procedures for addressing financial and other conflicts of interest
- Prohibit research with prisoners of war (POW)
- Comply with all provisions for research with human subjects using investigational test articles (drugs, device, and biologics)
- Follow recordkeeping requirements
- Support oversight by the sponsoring DoD Component (which may include DoD Component review of the research and site visits)

Part 5
DESIGNATION OF IRB(S) THAT WILL REVIEW DOD-SUPPORTED RESEARCH

All of the IRBs supporting the institution do not need to be listed in Tables 1 and 2. List only those IRBs that will review DoD-supported research.

A. IRB(s) that are Part of this Institution

In Table 1, identify each IRB that is organizationally part of this institution and can review DoD-supported research under this Addendum to the FWA (the IRBs should also be listed on the FWA). For each IRB listed in Table 1, the IRB Chair must sign this Addendum in Part 6. When requested by the DoD-sponsor, attach the membership list for each IRB listed (in accordance with 45 CFR 46); see Table 3 for an example.

Table 1. IRB(s) within the Institution

IRB Name or Number	DHHS IRB Registration Number (8 digits)
1. U of W – A	IRB 00000241
2.	
3.	
4.	

B. IRB(s) that are not Part of this Institution

In Table 2, identify each IRB that is not associated with this institution and can review DoD-supported research under this Addendum to the FWA. For each IRB listed in Table 2, attach the DoD Institutional Agreement for IRB Review (or an equivalent agreement). When requested by the DoD-sponsor, attach the membership list for each IRB listed (in accordance with 45 CFR 46); see Table 3 for an example.

Table 2. IRB(s) not part of this Institution

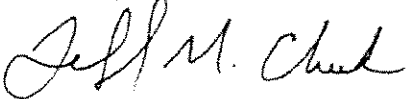
IRB Name or Number	DHHS IRB Registration Number (8 digits)*	Name of the Institution Providing the IRB	DoD Assurance Number of the Institution*	DHHS FWA Number of the Institution*
1. none				
2.				
3.				
4.				
5.				
6.				

* If applicable.

INSTITUTIONAL AGREEMENT

A. 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 its FWA and this Addendum, I assure protections for human subjects as specified above.

Signature:  Date: 3/4/2009

Name: Jeffrey M. Check

Rank/Grade: Not applicable Telephone number: 206-543-6619

Institutional Title: Associate Vice Provost for Research Compliance & Operations
FAX number: 206-685-9210

Mailing Address: Box 351202 Email address:
University of Washington jcheck@u.washington.edu
Seattle, WA 98195-1202

B. Chair(s) of the IRB(s) that are part of the Institution and listed in Table 1

Acting in an authorized capacity on behalf of this institution's IRB(s) and with an understanding of the IRB's responsibilities under the institution's FWA and this Addendum, I assure protections for human subjects as specified above.

Signature:  Date: 3/4/2009

Name: Zane A. Brown, MD Telephone number: 206-543-3714

Institutional Title: Professor of Perinatal Medicine, Obstetrics & Gynecology
FAX number: 206-616-9479

Institution: University of Washington Email address:
zbrown@u.washington.edu

Name(s) or Number of IRB: IRB00000241, named U of W - A

Mailing Address (if different from the Institutional Official above):
Box 356460, University of Washington, Seattle, WA 98195-6460

Note: If there are multiple IRBs listed in Table 1, each Chair should sign this Addendum and provide the information in this section. If a Chair presides over multiple IRBs listed in Table 1, provide the name and number of each IRB in this section.

C. Primary Contact - Human Research Protection of the FWA Institution

Name: Karen E. Moe Telephone number: 206-543-7246

Rank/Grade: not applicable FAX number: 206-543-9218

Institutional Title: Director, Human Subjects Division Email address:
kemoe@u.washington.edu

Mailing Address (if different from the Institutional Official above):
Box 359470, University of Washington, Seattle, WA 98195-9470

**PART 6
AIR FORCE HEADQUARTERS APPROVAL**

On behalf of the Air Force Surgeon General, I hereby approve this Air Force Issued DoD Addendum to the FWA.

DOD ADDENDUM # F50320 TO THE FWA #00006878

Signature:  Date: 6 Mar 09

Name: ROBERT N. KANG Lt Col, USAF, BSC

Address: HQ USAF/SGRC
5201 Leesburg Pike, Suite 1501B
Falls Church, VA 22041

This Addendum expires **three years** from the date of its approval. It must be updated regularly subject to a change in signatory official. For its uninterrupted continuation, this Assurance must be renegotiated with HQ USAF/SGRC prior to its expiration.

Expiration Date: 5 Mar 2012