



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

JAN 8 2009

MEMORANDUM FOR UNIVERSITY OF LOUISVILLE

ATTN: Manuel Martinez, M.D., Executive Vice-President for Research

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 00002211

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>
F50309	All research with human subjects performed by the University of Louisville and conducted or supported by the Air Force

My office has reviewed and approved Addendum coverage for the following protocol:

1. FOS20080005H, "Enhancing the Utility of Spatial Auditory Displays for Military Applications".

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 # F50309

{2/19/2007 version}

**Department of Defense
Human Research Protection Program**

**AIR FORCE ISSUED DEPARTMENT OF DEFENSE (DOD) 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-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 Louisville
Mailing Address: MedCenter One, Suite 200
501 E. Broadway
Louisville, KY 40202

Department of Health and Human Services (DHHS) FWA Number: FWA#00002211

C. Scope:

This Addendum applies to:

- A single research protocol only (list title and other identifying information);
 A group of research protocols (describe here or attach list);
 All DoD-supported research protocols performed by this Institution.

gc - see following page.

Candia, Jessica Civ AF/SGRC

From: Manuel Martinez [m0mart10@louisville.edu]
Sent: Monday, November 10, 2008 9:06 AM
To: Candia, Jessica Civ AF/SGRC
Cc: John D Burke
Subject: AF DOD Addendum

Jessica Candia, CIV, DAF, CIP
Program Manager, Research Oversight & Compliance Division HQ USAF/SGRC Office of the Surgeon
General
5201 Leesburg Pike, Suite 1501B
Falls Church, VA 22041

Dear Ms. Candia:

Please reduce the scope of the AF Issued DoD Addendum with the University of Louisville from:
"All DoD-supported protocols performed by this institution." to: "A group of research
protocols" described as "All research with human subjects performed by this institution and
conducted or supported by the Air Force".

Sincerely,

Manuel Martinez-Maldonado, MD, MACP
Executive Vice President for Research
University of Louisville
Phone: (502)-852-8372

Part 2 DEPARTMENT OF DEFENSE (DOD) REGULATIONS AND GUIDANCE

This institution assures it shall comply with the following laws, regulations, and guidance when conducting 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* Parts 50, 56, 312, and 812, (21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812) Food and Drug Administration 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"
- DoD Instruction (DoDI) 3210.07, "Research Integrity and Misconduct"
- DoDD 6200.02, "Use of Investigational New Drugs in Force Health Protection"

Part 3 DOD COMPONENT SPECIFIC REQUIREMENTS

This Institution will ensure that all of its activities associated with research involving human subjects will comply with Air Force Instruction 40-402 (AFI 40-402), Protection of Human Subjects in Research.

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 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)
- Record keeping requirements
- Oversight by the sponsoring DoD Component (which may include DoD Component review of the Research and site visits)

Part 5 INSTITUTIONAL AGREEMENT

Complete Part 5A if your Institution will be relying on an IRB(s) within your own institution for DoD-supported research. Complete Part 5B, if your Institution will be relying on an IRB belonging to another institution (this IRB shall be identified on the FWA and both parties shall have a DoD Institutional Agreement for IRB Review).

Part 5A Institutional Agreement: Institution with its own IRB(s)

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: Manuel Martínez, M.D.

Institutional Title: Executive Vice-President for Research

Mailing Address: Office of the Executive Vice President for Research
University of Louisville
Jouett Hall
2301 South Third Street
Louisville, KY 40292

Telephone number: 502-852-8373

FAX number: 502-852-8375

Email address: m0mart10@louisville.edu

Chair of the IRB(s) 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: 10/23/08

Name: Laura L. Clark, M.D.

Institutional Title: Professor Term Anesthesiology, Chair, Biomedical IRB

Mailing Address: Human Subjects Protection Program

MedCenter One, Suite 200

501 E. Broadway

Louisville, KY 40202

Telephone number: 502-852-5188

FAX number: 502-852-2164

Email address: mickai@aol.com

Signature:  Date: 10/17/08

Name: Patricia K. Leitsch, Ph.D.

Institutional Title: Assistant Professor ED-Leadership, Found. & HR Ed, Chair, SBE IRB

Mailing Address: Human Subjects Protection Program

MedCenter One, Suite 200

501 E. Broadway

Louisville, KY 40202

Telephone number: 502-852-5188

FAX number: 502-852-2164

Email address: pat.leitsch@louisville.edu

Note: If more than one Institutional IRB will be reviewing research under this Addendum, each IRB Chair shall sign and provide the requested information in this section.

Primary Contact - Human Research Protection

Signature:  Date: 10-10-2008

Name: John D. Burke, M.A., R.Ph.

Institutional Title: Director, Human Subjects Protection Program

Mailing Address: Human Subjects Protection Program

MedCenter One, Suite 200

501 E. Broadway

Louisville, KY 40202

Telephone number: 502-852-5188

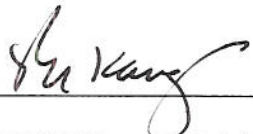
FAX number: 502-852-2164

Email address: jdburk04@louisville.edu

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 TO THE FWA: # F50309

Signature:  Date: 8 Jan 2009

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: 7 Jan 2012