



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

JAN 28 2008

MEMORANDUM FOR HQ USAFA/CC
ATTN: JOHN F. REGNI, LT GEN, USAF

FROM: HQ USAF/SGRC
110 Luke Ave, Suite 405
Bolling AFB DC 20032-7050

SUBJECT: Renewal of DoD Assurance of Compliance #50046

Attached is a signed copy of your Assurance of Compliance with TITLE 32 CODE OF FEDERAL REGULATIONS PART 219, FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS for the period of 28 Jan 2008 to 27 Jan 2011. Please maintain this document with your complete DoD Assurance.

Institutional Review Board membership lists should be updated as necessary and submitted to our office at least annually.

Thank you for your cooperation. If you have any questions, please do not hesitate to contact the undersigned at (202) 767-4331, DSN 297, telefax number is (202) 767-5302, DSN 297 or joe.narrigan@pentagon.af.mil.


JOSEPH J. NARRIGAN
Lt Col, USAF, BSC
Director, Research Oversight/Compliance Division
Office of the Surgeon General

Attachment:
Signed DoD Assurance

**Department of Defense
Human Research Protection Program**

**AIR FORCE ISSUED DOD ASSURANCE FOR THE PROTECTION OF
HUMAN RESEARCH SUBJECTS**

BY AN AIR FORCE INSTITUTION

**Part 1
AIR FORCE INSTITUTION INFORMATION**

A. Purpose of DoD Assurance:

- New
 Renewal for DoD Assurance Number: 50046

B. Institution Information:

Name: HQ USAFA
DoD Component: Air Force
Mailing Address: 2304 Cadet Drive, Suite 3300, USAFA CO 80840
Department of Health and Human Services (DHHS) Federalwide Assurance (FWA)
Number [if applicable]: N/A

C. Scope:

The Assurance applies to:

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

**Part 2
ETHICAL PRINCIPLES, COMPLIANCE, AND
RESPONSIBILITIES OF THE INSTITUTION**

The Institutional Official, acting in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, will ensure protection of human subjects as specified below.

A. Ethical Principles of the Institution:

This Institution (e.g., the Institutional Official, the Institutional Review Board

(IRB), IRB office staff, investigators and research staff, and other institutional personnel supporting research covered under this Assurance) will ensure that all of its activities associated with research involving human subjects (as defined by Title 32 *Code of Federal Regulations* Part 219 (32 CFR 219)) are guided by the ethical principles set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the *Belmont Report*).

2. This Institution recognizes the principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice, as stated in the *Belmont Report*, and will act in accordance with these principles in all research covered by this Assurance.

3. This Institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human research subjects.

B. Institutional Compliance with Regulations and Policies:

1. This Institution will comply with 32 CFR 219; Title 10 *United States Code* Section 980 (10 USC 980); DoD Directive 3216.02 (DoDD 3216.02); 45 CFR Part 46 (Subparts B, C, and D as made applicable by DoDD 3216.02), the Food and Drug Administration policies (e.g., 21 CFR Parts 50, 56, 312, and 812) where applicable; and any other applicable federal, state, and local laws.

2. This Institution will comply with the requirements of the DoD Component identified above in Part 1 governing the protection of human subjects. These requirements are identified in Part 3 of this Assurance. DoD Components may require that other research, not specifically identified by 32 CFR 219, also comply with the terms of this Assurance (32 CFR 219.101(d)).

3. When this Institution conducts research supported by or in collaboration with an organization of another DoD Component or another Federal Department or Agency, this Institution also may be required to comply, through a separate agreement, with the policies and procedures of that organization. The supporting or collaborating DoD Component, Federal Department, or Federal Agency will inform the Institution of any additional requirements.

4. Except when research is exempt from the requirements of 32 CFR 219, or applicability of 32 CFR 219 is waived under 32 CFR 219.101, this Assurance applies to all research involving human subjects and all other activities related to such research even in part, regardless of whether the research is otherwise subject to federal regulation, if:

a. the research is conducted by or under the direction of any employee of this Institution in connection with Institutional responsibilities; or

b. the research is conducted by or under the direction of any employee of this Institution using any property or facility of this Institution; or,

c. the research involves the use of this Institution's nonpublic information for any purpose of the research, including but not limited to identifying or contacting prospective human research subjects.

5. Applicability of the terms of this Assurance is not restricted by other considerations such as location of research, funding source (e.g., intramural or extramural to DoD), funding appropriation, nature of support, program budget activity (e.g., Major Force Program 6, Research and Development, or Major Force Program 8, Defense Health Program), program title, or security classification. Additional requirements specific to DoD Component may be outlined in Part 3 of this Assurance.

6. If this Institution collaborates with other investigator(s) who are not employed by an institution with a federal assurance, this Institution may extend the applicability of this Assurance to the collaborating investigator(s). This collaborative agreement will be documented by both parties using a DoD Individual Investigator Agreement (or an equivalent agreement) in accordance with policies of the DoD Component that approves this Assurance.

7. Research involving human subjects may not begin until (1) this DoD Assurance covering the research is approved by the DoD Component; (2) the research is recommended for approval by an IRB listed on this DoD Assurance; and (3) the research is approved by the Institutional Official.

C. Responsibilities of the Institution:

1. Responsibilities of the Institutional Official:

a. The Institutional Official will maintain a Human Research Protection Program (HRPP) that provides policies and procedures on implementing the federal, state, and local policies referenced in this Assurance. The Institutional Official will monitor and ensure compliance with the HRPP.

b. The Institutional Official bears full responsibility for the conduct of research covered by this Assurance with respect to compliance with applicable federal, state, and local laws.

c. Some of the responsibilities of the Institutional Official are identified below. The complete list of requirements for compliance is provided above in Part 2, Section B, Institutional Compliance with Regulations and Policies, and below in Part 3, DoD Component Specific Requirements, of this Assurance.

i. The Institutional Official will provide resources to execute the Institution's HRPP, including but not limited to: continuing education and training for personnel involved in the HRPP; meeting space for its own IRB(s); and staff sufficient to support such HRPP functions such as IRB review, record-keeping, and oversight of research.

ii. The Institutional Official will ensure that HRPP policies require scientific review of research protocols and that it is considered during the review and approval process.

iii. The Institutional Official will ensure that the HRPP implementing policy and procedures include language requiring prompt reporting of (a) unanticipated problems involving risks to subjects or others, (b) serious or continuing non-compliance, (c) suspension or termination of IRB approval, and (d) any other events or circumstances requiring notifications.

2. Responsibilities of the Institutional Review Board (IRB):

a. The IRB will maintain standard operating policies and procedures, as part of the Institution's HRPP, to comply with the terms of this Assurance.

b. Some of the responsibilities of the IRB are identified below. The complete list of requirements for compliance is provided above in Part 2, Section B, Institutional Compliance with Regulations and Policies, and below in Part 3, DoD Component Specific Requirements, of this Assurance.

i. The IRB will comply with its written Institutional procedures for the following actions: (a) initial and continuing review of research; (b) reporting of findings and actions to the investigator and to the Institutional Official; (c) determination of research requiring IRB review more frequently than annually; and (d) identification of research requiring verification from sources other than the investigators that no material changes have occurred since previous IRB review.

ii. Except when an expedited review procedure is used (see 32 CFR 219.110), the IRB will review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. Approval of the research requires the approval of a majority of those members present at the meeting.

iii. The IRB will identify unique risks associated with involving DoD civilian or military employees as research subjects and minimize risks or the magnitude of harm.

3. Responsibilities of the Research Investigators:

a. Some of the responsibilities of the investigators are identified below. The complete list of requirements for compliance is provided above in Part 2, Section B, Institutional Compliance with Regulations and Policies, and below in Part 3, DoD Component Specific Requirements of this Assurance.

i. Investigators will acknowledge and accept responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this Assurance.

ii. Investigators will obtain written determination that the proposed activity meets the definition of research. If it is found to be research, investigators then will secure written determination that it involves human subjects, and, if so, whether it meets the criteria for an exemption as defined in the federal regulations for human subject protections in accordance with the Institution's HRPP.

iii. Investigators shall promptly report to the IRB proposed changes in a research activity and shall ensure that such changes in approved research, during the period for which IRB approval has already been given, are not initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

iv. Investigators will comply with all policies and procedures of the Institution's HRPP.

Part 3
DOD COMPONENT SPECIFIC REQUIREMENTS
Department of the Air Force

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

Part 4
DESIGNATION OF INSTITUTIONAL REVIEW BOARDS (IRB)

A. Institutional IRB(s)

Table 1 identifies all of the DoD IRB(s) associated with this Institution that will or may review research under this Assurance. For each IRB listed, the membership list (in accordance with 32 CFR 219) is also attached to this Assurance (see Table 3).

Table 1. Institutional IRB(s)

Name or Number of DoD IRB	DHHS IRB Registration Number (if applicable)
1. HQ USAFA 50046	N/A
2.	

B. IRB(s) not Part of this Institution

Table 2 (if applicable) identifies any IRBs that are not associates with this Institution but will or may review research under this Assurance. For each IRB listed in Table 2, the DoD Institutional Agreement for IRB Review (or an equivalent agreement) is attached to this Assurance.

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

Name of Institution	DoD Assurance Number	Name or Number of IRB	DHHS/FWA Number (if applicable)	DHHS IRB Registration Number (if applicable)
1.				
2.				
3.				
4.				

Part 5

INSTITUTIONAL POLICIES AND PROCEDURES

This Institution's HRPP maintains policies and procedures that describe how the Institution's HRPP will execute the requirements listed in Parts 2 and 3 of this Assurance and how the Institution and its IRB(s) will review, conduct, and oversee research with human subjects.

Institutional HRPP policies and procedures (e.g., regulations, instructions, guidelines, and standard operating procedures) are as follows:

1. USAFA Supplement to AFI 40-402
2. USAFA Policies and Procedures
3. AFI 40-402

Part 6

INSTITUTIONAL ASSURANCE

A. Institutional Official Assurance

Acting in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above.

Signature:



Date: 4 JAN 2008

Name: JOHN F. REGNI

Rank/Grade: Lt. Gen.

Institutional Title: Superintendent

Mailing Address: 2304 Cadet Drive, Suite 3300, USAFA CO 80840

Telephone number: 719-333-4140

FAX number: 719-333-4146

Email address: John.Regni@usafa.af.mil

B. Chair of the IRB(s) Listed in Table 1

Acting in an authorized capacity on behalf of this Institution's IRB(s) and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. As Chair of the IRB(s) designated above in Table 1, I will provide oversight for all research approved by this IRB(s) and conducted under this Assurance.

Signature:  Date: 10 Dec 07

Name: KATHERINE SILZ-CARSON
Rank/Grade: AD-23
Institutional Title: Chair
Mailing Address: 2354 Fairchild Hall, Suite 6K148, USAFA CO 80840
Telephone number: 719-333-2597
FAX number: 719-333-7137
Email address: kate.carson@usafa.edu

Note: Chair of each IRB identified in Table 1 will complete Section B.

C. Primary Contact - Human Research Protection

Name: GAIL B. ROSADO
Rank/Grade: GS-09
Institutional Title: IRB Administrator
Mailing Address: 2304 Cadet Drive, Suite 3800, USAFA CO 80840
Telephone number: 719-333-6593
FAX number: 719-333-4309
Email address: gail.rosado@usafa.af.mil

Table 3. Institutional IRB Membership List
 IRB's Name: HQ USAFA Date: 26 November 2007

DoD IRB # (if applicable): _____ DHHS IRB # (if applicable): _____

Institution Name: HQ USAFA DoD Assurance Number: 50046

Rank/Title	Last Name	First Name	M I	Gender (M/F)	Affiliated? (Y/N)	Eamed Degrees	Professional Expertise/ Experience (indicate Non Scientist by NS)	Name of Institution for Non-affiliated
Primary Members								
1. IRB Chair	Silz-Carson	Katherine	S	F	Y	PhD	Economics	
2. Vice Chair	O'Donnell	Kathleen		F	Y	PhD	Experimental Psychology	
3. Institutional Policy/Administrator	Rosado	Gail	B	F	Y			
4. Institutional Policy	Putnam	John		M	Y	PhD	Entomology	
5. Legal	Rieder	John	P	M	Y	JD	Judge Advocate	
6. Professional Standards	Tokish	John		M	Y	MD	Orthopedic Surgeon	
7. Scientist	Brothers	Michael		M	Y	PhD	Integrative Physiology	
8. Non Affiliated	Nicholson	Mary	E.	F	N	BS	EEO Specialist	21 SW
9. Cadet Wing Rep	Gibson	Frederick		M	Y	PhD	Industrial/Organ. Psychology	
10. Cadet Rep	Levy	Hila		F				
Alternates for Primary Members								
(Alternate for Member name/number)								
1. Legal	Murphy	James	J	M	Y	JD	Judge Advocate	
2. Professional Standards	Wilson	Candy		F	Y	PhD	Nursing Science	
3. Scientist	Westmoreland	David		M	Y	PhD	Animal Ecology	
4. Non Affiliated	Bishop	Nancy		F	N	BA/MA	Political	21 SW/XP

DEPARTMENT OF DEFENSE

*** Assurance Number: DoD A50046**

United States Air Force Academy (USAF Academy), Colorado

All parts of this Assurance are in compliance with requirements of Title 32 Code of Federal Regulations Part 219 (32 CFR 219); 10 U.S. Code 980; AFI 40-402; DoDD 3216.02; and where applicable 21 CFR 50, 21 CFR 56 and 45 CFR 46 (Subparts B, C, and D) under the authority of the Department of Defense (DoD).

DoD Approving Official:


JOSEPH J. NARRIGAN
Lt Col, USAF, BSC
Director, Research Oversight/Compliance Division
Office of the Surgeon General

Date: JAN 28 2008

Mailing Address for Communications Regarding this Assurance:

HQ USAF/SGRC
110 Luke Ave, Suite 405
Bolling AFB DC 20032-7050

Telephone: (202) 767-4331
Facsimile: (202) 767-5302

*Expiration Date: 27 JUN 2011

*This assurance expires **three years** from the date of its approval. It must be updated regularly subsequent to a change of the signatory official, the IRB Chair, the IRB membership, or of the policies and procedures to maintain this DoD Assurance file current. A revised and dated IRB membership roster must be submitted if there is a change in the IRB membership. For its uninterrupted continuation, this Assurance must be renegotiated with the Office of the United States Air Force Surgeon General via the Director, Research Oversight and Compliance Division, prior to its expiration.