DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE

WASHINGTON DC

JUN 23 2014

MEMORANDUM FOR UNIVERSITY OF FLORIDA
ATTN: DAVID NORTON, PH.D.
VICE PRESIDENT FOR RESEARCH

FROM: AFMSA/SGE-C
Research Oversight & Compliance Division
7700 Arlington Blvd. Ste 5151
Falls Church, VA 22042-5151

SUBJECT: Approval of AF Issued DoD Addendum to the Department of Health and Human Service's Federalwide Assurance (FWA) Number 00005790

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) DoDI 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research

On behalf of the Air Force Surgeon General, your DoD Addendum to the above FWA is approved. Your institution's assigned DoD Addendum number and covered human research are as follows:

DoD Number	**Research Covered**
F50551	**"All DoD-Supported Human Research Protocols Performed by this Institution."**

This Addendum must be updated regularly subject to a change in signatory official. For its uninterrupted continuation, this Addendum must be renegotiated with AFMSA/SGE-C prior to its expiration, which is **12 December 2018**.

Please maintain a copy of the attached approved Addendum with your research records.

In order to comply with this Addendum, you must provide to this office a copy of all continuing review reports submitted to the IRB in addition to the reports required by the above references.

Thank you for your cooperation in this matter. Please feel free to contact me at 703-681-6277 or afmsa.sge.c@pentagon.af.mil for additional assistance.

JAMES BENJACK, Lt Col, USAF, BSC
Director, Research Oversight & Compliance Division

Attachment: DoD Addendum #**F50551**

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

General Instructions to Institutions

- This form is a tool to help Institutions with an existing FWA approved by DHHS to know about and acknowledge key DoD policies and requirements since the DHHS FWA does not identify DoD requirements.
- Contact your DoD Component Sponsor for guidance if you have questions.
- Complete and print your Addendum on your Institution's letterhead.
- Follow your DoD Component Sponsor's instructions for paper or electronic submission.
- Part 1, A. If you need to update an existing Addendum, contact your DoD Component Sponsor for guidance.
- Part 1, B. Description of the Institution: List any organizations under the jurisdiction of the Institution that are well known and describe the kinds of research areas that will be covered by this Addendum.
- Part 3. All of the DoD Components' top-level policies are listed in this section. This is so that this one Addendum can be submitted by the Institution and approved by one DoD Component on behalf of the entire DoD.
- Part 5. Complete Section A for all IRB(s) used by your Institution IF the IRB is part of your Institution. Complete Section B for all IRB(s) used by your Institution if the IRB is NOT part of your Institution. For each IRB in Section B, attach your DoD Institutional Agreement for IRB Review (or equivalent agreement) to your Addendum. 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.
- Part 6. The "Official Legally Authorized to Represent the FWA Institution" is the person who signed the FWA as the Institutional Official.

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

[X] New
[ ] Renewal for DoD Addendum Number:

B. Institution Information

Name: University of Florida
DHHS FWA Number: 00005790
Description of the Institution: UF is a major, public, comprehensive, land-grant, research university.

C. Scope

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

Limitation of Scope (if 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 DoD Instruction (DoDI) 3216.02
- Title 21 Code of Federal Regulations 50, 56, 312, and 812, Food and Drug Administration (FDA) Regulations
- 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"
- 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. IRB-01	IRB00000335
2. IRB-02	IRB00000336
3. IRB-03	IRB00000337
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.				
2.				
3.				
4.				
5.				
6.				

* If applicable.

Part 6
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 it's FWA and this Addendum, I assure protections for human subjects as specified above.

Signature: _____ Date: 5-22-14

Name. David Norton, PhD
Rank/Grade: Telephone number: (352) 392-9271
Institutional Title: Vice President for Research FAX number: (352) 846-0491
Mailing Address: Box 11500, Gainesville, FL 32611 Email address:
dpnorton@ufl.edu

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: 5-6-14

Name: R. Peter Iafrate, PharmD Telephone number: (352) 273-9612
Institutional Title: IRB-01 Chairman FAX number: (325) 273-9614
Institution: University of Florida Email address: iafrar@shands.ufl.edu
Name(s) or Number of IRB: IRB-01 / IRB00000335
Mailing Address (if different from the Institutional Official above):
Box 100173, Gainesville, FL 32610

Signature: _____ Date: 5-22-2014

Name: Ira Fischler, PhD Telephone number: (352) 392-0433
Institutional Title: IRB-02 Chairman FAX number: (352) 392-9234
Institution: University of Florida Email address: ifisch@ufl.edu
Name(s) or Number of IRB: IRB-02 / IRB00000336
Mailing Address (if different from the Institutional Official above):
Box 112250, Gainesville, FL 32611

Signature: _____ Date: 5/13/14

Name: Alan Halperin, MD
Institutional Title: IRB-03 Chairman
Institution: University of Florida
Name(s) or Number of IRB: IRB-03 / IRB00000337
Telephone number: (904) 244-3155
FAX number: (904) 244-9035
Email address: alan.halperin@jax.ufl.edu
Mailing Address (if different from the Institutional Official above):
UF College of Medicine – Jacksonville
9th Floor, Tower II
580 West 8th Street
Jacksonville, FL 32209

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: Michael Mahoney
Rank/Grade:
Institutional Title: Director or Research Operations & Services
Telephone number: (352) 294-2744
FAX number: (352) 846-0491
Email address: mmahoney@ufl.edu
Mailing Address: Box 115500, Gainesville, FL 32611
(if different from the Institutional Official above):

FWA #: **FWA00005790**
Institution: **U of Florida**
Expires: **12/12/2018**

OMB No. 0990-0278
Approved for use through June 30, 2014

Federalwide Assurance (FWA) for the Protection of Human Subjects

1. Institution Filing Assurance

Legal Name: **U of Florida**

City: **Gainesville** State/Province: **FL** Country: **USA**

2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)	
U of Florida	**Jacksonville**	FL	A
university of florida	**Gainesville**	FL	A

3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of the source of support, will be guided by the following statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. (indicate below)

The Belmont Report

4. Applicability

(a) This Assurance applies whenever this Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule or the department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.

(b) Optional: This Institution elects to apply the following to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance:

The Common Rule (see section 3 of the Terms of the FWA for a list of U.S. federal departments and agencies that have adopted the Common Rule and the applicable citations to the Code of Federal Regulations)

5. Assurance of Compliance with the Terms of the Federalwide Assurance

(a) This Institution assures that whenever it engages in research to which this Assurance applies, it will comply with the Terms of the Federalwide Assurance (contained in a separate document on the Office for Human Research Protections (OHRP) website).

6. Designation of Institutional Review Boards (IRBs)

This Institution assures that it will rely upon only IRBs registered with OHRP for review of research to which this FWA applies. This institution (a) designates the following internal IRB(s) for review of research under this Assurance; or (b) does not have an internal IRB and designates the following external IRB for review of all research to which this FWA applies or, if multiple external IRBs are relied upon, the following external IRB that reviews the largest percentage of research to which this FWA applies.

NOTE: Institutions designating internal IRBs do not need to designate any of the external IRBs upon which it relies.

HHS IRB Registration Number	Name of IRB as Registered with HHS	Is the IRB Internal or External to the Institution?
IRB00000021	Fred Hutchinson Cancer Rsch Ctr IRB #1 - Biomedical Research	E
IRB00000022	Fred Hutchinson Cancer Rsch Ctr IRB #2 - Biomed/HVTN/Inf. Disease	E
IRB00000335	U of Florida IRB #1	I
IRB00000336	U of Florida IRB #2	I
IRB00000337	U of Florida IRB #3	I
IRB00000456	State of Florida Dept of Hlth IRB #1	E
IRB00000533	Western IRB #1-5, 16, & #35 - All U.S. Panels	E
IRB00005334	State of Florida Dept of Hlth IRB #2	E
IRB00005619	Fred Hutchinson Cancer Rsch Ctr IRB #3 - PHS & Behavioral Rsch	E

7. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: Michael Middle Initial: P Last Name: Mahoney

Degrees or Suffix: BA Institutional Title: Asst Director

Institution: University of Florida

Telephone: 352 273-9600 FAX: 352 273-9614 E-Mail: mmahoney@ufl.edu

Address: PO Box 100173

City: Gainesville State/Province: FL Country: USA

8. Signatory Official (i.e., Official Legally Authorized to Represent the Institution)

I have read and agree to the Terms of the Federalwide Assurance.

I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education and training about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially 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. The IRB(s) that this institution relies upon will comply with the Terms of the Federalwide Assurance when reviewing research covered by this Assurance and possess appropriate knowledge of the local context in which this Institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.

Signature: **David P Norton Ph. D.**

Date: **12/12/2013**

First Name: **David** Middle Initial: **P** Last Name: **Norton**

Degrees or Suffix: **Ph. D.** Institutional Title: **Vice President**

Institution: **University of Florida**

Telephone: **352 392-9271** FAX: **352 846-0491** E-Mail: **dpnorton@ufl.edu**

Address: **PO Box 115500**

City: **Gainesville** State/Province: **FL** Country: **USA**

9. FWA Approval

The Federalwide Assurance for the Protection of Human Subjects for Institutions Within the United States submitted to HHS by the above Institution is hereby approved.

Assurance Number: **FWA00005790** Expiration Date: **12/12/2018**

Signature of HHS Approving Official: **Jean Makle** Date: **12/12/2013**