



DEPARTMENT OF THE NAVY
OFFICE OF THE CHIEF OF NAVAL OPERATIONS
2000 NAVY PENTAGON
WASHINGTON, D.C. 20350-2000

IN REPLY REFER TO
3900
Ser N093/0033
4 Mar 2013

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

DoD-Navy FWA Addendum: DoD N-A3141

Expiration Date: 17 November 2016

Institution: Wake Forest University Health Sciences

The application for the Department of Defense - Navy Addendum to the Federalwide Assurance, FWA00001435, held by Wake Forest University Health Sciences, is approved.

In accordance with the signed Addendum, Wake Forest University Health Sciences and the Institutional Review Board (IRB) listed in the Addendum or in the associated Institutional Agreement(s) for IRB Review, agree to abide by the Department of Defense's and the Department of the Navy's regulations and policies for the protection of human research participants when conducting, reviewing, approving, overseeing, supporting, or managing Navy-supported research with human subjects.

Communications regarding this Addendum should be addressed to:

Bureau of Medicine and Surgery
Department of the Navy
Human Research Protection Program (M00RPH)
7700 Arlington Blvd., Suite 5121
Falls Church, VA 22042-5121
Telephone: 703-681-9629, Fax: 703-681-2597
Email: human.research@med.navy.mil

A handwritten signature in black ink, appearing to read "A. F. Nordholm".

A. F. NORDHOLM
Captain, Medical Service Corps
United States Navy
Director, Department of the Navy
Human Research Protection Program
By Direction of the Surgeon General of the Navy

Attachment:

Wake Forest University Health Sciences DoD-Navy FWA Addendum application dtd 7 Feb 2013

**Department of Defense
Department of the Navy
Human Research Protection Program**

**DEPARTMENT OF DEFENSE (DOD)-DEPARTMENT OF THE NAVY (DON) ADDENDUM
TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES 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-DON supported human subject research.

**Part 1
INSTITUTION INFORMATION**

A. Purpose of DoD-DON Addendum:

- New
 Renewal for DoD-DON Addendum Number: N-A3141
 Update for DoD-DON Addendum Number: _____
DoD-DON Addendum Expiration Date: _____

B. Institution Information:

Name: Wake Forest University Health Sciences
Mailing Address: 1 Medical Center Boulevard Winston-Salem, NC 27157
Department of Health and Human Services (DHHS) FWA Number: FWA00001435
FWA Expiration Date: 11/17/2016

C. Scope:

This Addendum applies to all DoD-DON supported research protocols performed by this Institution.

D. Effective Date:

This Addendum is effective as of the date the approval document is signed by the Navy Surgeon General and expires on the date listed in the approval document.

Part 2
DEPARTMENT OF DEFENSE (DOD) REGULATIONS AND GUIDANCE

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:

- 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 DoDI 3216.02
- Title 21 Code of Federal Regulations 50, 56, 312, and 812, Food and Drug Administration (FDA) Regulations
- DoD Instruction (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"
- DoDI 3210.7, "Research Integrity and Misconduct"
- DoDI 6200.02, "Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs"

Part 3
DOD COMPONENT SPECIFIC REQUIREMENTS

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

National Geospatial Intelligence Agency

National Security Agency

Defense Intelligence Agency

Defense Threat Reduction Agency

Defense Advanced Research Projects Agency

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 Guidance 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)
- Recordkeeping requirements
- Oversight by the sponsoring DoD Component (which may include DoD Component review of the research and site visits)

Part 5
DESIGNATION OF INSTITUTIONAL REVIEW BOARDS (IRB) THAT WILL REVIEW
DoD-DON-SUPPORTED RESEARCH

A. Institutional IRB(s)

Table 1 identifies the IRB(s) associated with this Institution that will or may review DoD-supported research under this Addendum to the FWA.

For each IRB listed below, the IRB Chair(s) must sign and list the corresponding IRB number(s) in Part 6 of this Institutional Agreement.

Table 1. Institutional IRB(s)

Institutional Name or Number of IRB	DHHS IRB Registration Number
1. Wake Forest U Hlth Sciences IRB #1	IRB00000212
2. Wake Forest U Hlth Sciences IRB #2	IRB00002432
3. Wake Forest U Hlth Sciences IRB #3	IRB00002433
4. Wake Forest U Hlth Sciences IRB #4	IRB00002434
5. Wake Forest U Hlth Sciences IRB #5	IRB00008492
6. Wake Forest U Hlth Sciences IRB #6	IRB00008493
7. Wake Forest U Hlth Sciences IRB #7	IRB00008494
8. Wake Forest U Hlth Sciences IRB #8	IRB00008495

B. IRB(s) not Part of this Institution

Table 2 (if applicable) identifies any IRBs that are not associated with this Institution but will or may review DoD-supported research under this Addendum to the FWA.

For each IRB listed in Table 2, the DoD Institutional Agreement for IRB Review must be attached to this Addendum to the FWA.

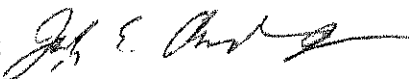
Table 2. DoD or non-DoD IRB(s) not Part of this Institution

Name of Institution	DoD Assurance Number	Name or Number of IRB	DHHS/FWA Number	DHHS IRB Registration Number
1.				
2.				
3.				
4.				
5.				
6.				

**Part 6
INSTITUTIONAL AGREEMENT**

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: January 28, 2013

Name: Joseph E. Andrews, Jr., PhD
Rank/Grade: Research Administration
Institutional Title: Director, IRB & HRPP
Mailing Address: 1 Medical Center Boulevard
Winston-Salem, NC 27157

Telephone number: 336-716-7658
FAX number: 336-716-9902
Email address: jandrews@wakehealth.edu

Chair(s) of the IRB(s) that will Review DoD-DON Supported Research on behalf of the FWA Institution

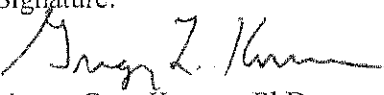
Acting in an authorized capacity on behalf of this Institution's IRB(s) and with an understanding of the Institution's responsibilities under its FWA and this Addendum, I assure protections for human subjects as specified above. As Chair of the IRB(s), I shall provide oversight for all research approved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

Signature: 

Date: 2/4/13

Name: Richard B. Weinberg, MD
Rank/Grade: Professor of Medicine
Institutional Title: Executive IRB Chair
& Chair Board I
Mailing Address: 1 Medical Center Boulevard
Winston-Salem, NC 27157

Telephone number: 336-713-7313
FAX number: 336-716-9902
Email address: weinberg@wakehealth.edu

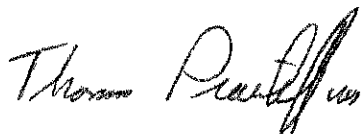
Signature: 

Date: 2/4/13

Name: Greg Kucera, PhD
Rank/Grade: Associate Director Tumor Tissue Core
Institutional Title: IRB Chair Board 2
Mailing Address: 1 Medical Center Boulevard
Winston-Salem, NC 27157

Telephone number: 336-716-6348
FAX number: 336-716-9902
Email address: gkucera@wakehealth.edu

Signature:

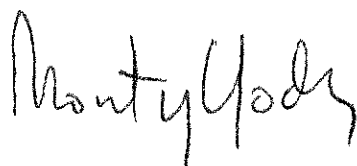


Date: 2/6/13

Name: Thomas Pranicoff, MD
Rank/Grade: Professor of Medicine
Institutional Title: IRB Chair Board 3
Mailing Address: 1 Medical Center Boulevard
Winston-Salem, NC 27157

Telephone number: 336-716-4542
FAX number: 336-716-9902
Email address: tpraniko@wakehealth.edu

Signature:



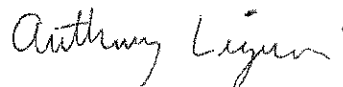
Date:

2/7/13

Name: Monty Yoder, PharmD
Rank/Grade: Clinical Specialist Cardiology Pharmacy
Institutional Title: IRB Chair Board 4
Mailing Address: 1 Medical Center Boulevard
Winston-Salem, NC 27157

Telephone number: 336-716-4542
FAX number: 336-716-9902
Email address: myoder@wakehealth.edu

Signature:

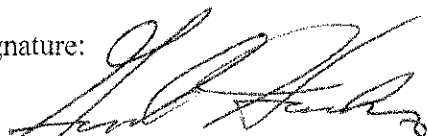


Date: 4-FEB-2013

Name: Anthony Liguori, PhD
Rank/Grade: Associate Professor Phys/Pharm
Institutional Title: IRB Chair Board 5
Mailing Address: 1 Medical Center Boulevard
Winston-Salem, NC 27157

Telephone number: 336-716-4542
FAX number: 336-716-9902
Email address: aliguori@wakehealth.edu

Signature:



Date:

2/7/13

Name: Gregory Hawkins, PhD
Rank/Grade: Assoc. Professor of Medicine
Institutional Title: IRB Chair Board 6
Mailing Address: 1 Medical Center Boulevard
Winston-Salem, NC 27157

Telephone number: 336-716-4542
FAX number: 336-716-9902
Email address: ghawkins@wakehealth.edu

Signature:



Date:

2/7/2013

Name: Alain Bertoni, MD

Rank/Grade: Assoc. Professor of Public Health

Institutional Title: IRB Chair Board 7

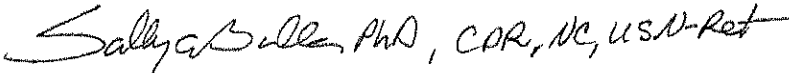
Mailing Address: 1 Medical Center Boulevard
Winston-Salem, NC 27157

Telephone number: 336-716-4542

FAX number: 336-716-9902

Email address: abertoni@wakehealth.edu

Signature:



Date: 1/31/13

Name: Sally Bulla, PhD

Rank/Grade: Nursing Research Associate

Institutional Title: IRB Chair Board 8

Mailing Address: 1 Medical Center Boulevard
Winston-Salem, NC 27157

Telephone number: 336-716-4542

FAX number: 336-716-9902

Email address: sbulla@wakehealth.edu

Note: Each IRB Chair of an IRB reviewing research under this Addendum shall sign and provide the requested information above.

Primary Contact - Human Research Protection of the FWA Institution

Signature: 

Date: 1/30/13

Name: J. Brian Moore, MS

Rank/Grade: Research Administration

Institutional Title: Asst. Director IRB & HRPP

Mailing Address: 1 Medical Center Boulevard
Winston-Salem, NC 27157

Telephone number:

FAX number:

Email address: jbmoore@wakehealth.edu