FWA #: **FWA00016277**

Institution: **General Dynamics Information Technology**

Expires: **09/02/2013**

OMB No. 0990-0278

Approved for use through May 31, 2011

Federalwide Assurance (FWA) for the Protection of Human Subjects for Institutions Within the United States

1. Institution Filing Assurance

Name of Organization: **General Dynamics Information Technology**

City: **Fairfax** State: **VA**

HHS Institution Profile File (IPF) code, if known:

Federal Entity Identification Number (EIN), if known:

If this Assurance replaces an MPA or CPA, please provide the "M" or "T" number:

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. The Institution should have available for review by the Office for Human Research Protections (OHRP) upon request a brief description and line diagram explaining the interrelationships among the Assurance Signatory Official, the Institutional Review Board(s) (IRB), IRB support staff, and investigators in these various components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below. Entities that the Signatory Official is not legally authorized to represent may not be listed here without the prior approval of OHRP.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)	Status

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 ethical principles in the following document(s): *(indicate below)*

The Belmont Report

4. Applicability

(a) This Institution assures that whenever it engages in human subjects research conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, the Institution will comply with the [Terms of the Federalwide Assurance for Institutions Within the United States (contained in a separate document on the OHRP website),] unless the research is otherwise exempt from the requirements of the Common Rule or a department or agency conducting or supporting the research has determined that the research shall be covered by 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 Institutions Within the United States for a list of departments and agencies that have adopted the Common Rule and the applicable citations to the Code of Federal Regulations)

5. Designation of Institutional Review Boards (IRBs)

This Institution designates the following IRB(s)/IEC(s) for review of research under this Assurance *(if the IRB(s)/IEC(s) has not previously registered with HHS or has not provided a membership roster to HHS, please submit to OHRP the appropriate IRB registration materials which are available on the OHRP website)*.

NOTE: Reliance on the IRB of another institution or organization or an independent IRB must be documented by a written agreement that is available for review by OHRP upon request. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the parties involved may develop their own agreement. Future designation of other IRBs requires an update of the FWA.

HHS IRB Registration Number	Name of IRB as Registered with HHS	Status
IRB00000790	Chesapeake Rsch Review, Inc. IRB #1 - General Panels 1-3 (MWF)	A

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

First Name: (b) (6) Middle Initial: (b) Last Name: (b) (6)
Degrees or Suffix: (b) (6) Organizational Title: (b) (6)
Institution: General Dynamics Information Technology
Telephone: (b) (6) (b) (6) (b) (6)

Address: (b) (6)

City: (b) (6) State: (b) (6) Zip Code: (b) (6)

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

I understand that the Assurance Training Modules on the OHRP website describe the responsibilities of the Signatory Official, the IRB Chair(s), and the Human Protections Administrator under this Assurance. Additionally, I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education 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) designated above are to provide review for all research to which this Assurance applies. The designated IRB(s) will comply with the [Terms of the Federalwide Assurance for Institutions Within the United States] 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: Date:

First Name: (b) (6) Middle Initial: Last Name: (b) (6)

Degrees or Suffix: Organizational Title: (b) (6)

Institution: **General Dynamics Information Technology**

Telephone: (b) (6) FAX: (b) (6) E-Mail: (b) (6)

Address: (b) (6)

City: (b) (6) State: (b) (6) Zip Code: (b) (6)

NOTE: Institutions operated by the U.S. Government may need to obtain department or agency clearance prior to submission of the FWA to OHRP. Please contact the relevant department or agency Human Subject Protections Officer before forwarding this Assurance to OHRP.

8. 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: **FWA00016277** Expiration Date: **09/02/2013**

Signature of HHS Approving Official: (b) (6) Date: **09/02/2010**

SW., Washington, DC 20201. *Do not return the completed form to this address.*

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 M00RP/12UM00RP190
18 May 2012

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

DoD-Navy FWA Addendum: DoD N-A3259

Expiration Date: 2 September 2013

Institution: General Dynamics Information Technology

The application for the Department of Defense - Navy Addendum to the Federalwide Assurance, FWA00016277, held by General Dynamics Information Technology, is approved.

In accordance with the signed Addendum, General Dynamics Information Technology 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:

Department of the Navy
Office of Research Protections (M00RP)
Bureau of Medicine and Surgery
2300 E Street, NW
Washington DC 20372-5300
Telephone: 202-762-0161, Fax: 202-762-0976
Email: human.research@med.navy.mil

(b) (6) [redacted]

Attachment:
General Dynamics Information Technology DoD-Navy FWA Addendum application dtd 20 Mar 2012

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 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-DON supported human subject research.

Part 1
INSTITUTION INFORMATION

A. Purpose of DoD-DON Addendum:

[X] New
[ ] Renewal for DoD-DON Addendum Number: _____
[ ] Update for DoD-DON Addendum Number: _____
DoD-DON Addendum Expiration Date: _____

B. Institution Information:

Name: General Dynamics Information Technology
Mailing Address: 3211 Jermantown Road, Fairfax, VA 22030
Department of Health and Human Services (DHHS) FWA Number: FWA00016277
FWA Expiration Date: 9/2/2013

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.	
2.	
3.	
4.	
5.	
6.	

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. Chesapeake Research Review, Inc.	N/A	IRB#1 – General Panels 1-3	N/A	IRB00000790
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.

(b) (6)

Date: 3/20/2012

Rank/Grade:

Telephone number: (b) (6)

(b) (6)

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 it's 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:

Name: N/A – see IAIR attached

Rank/Grade:

Institutional Title:

Mailing Address:

For IRB #(s):

Telephone number:

FAX number:

Email address:

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: (b) (6)

Date: March 15, 2012

Name: (b) (6)

Rank/Grade:

Telephone number:

(b) (6)

Department of Defense
Human Research Protection Program

DOD INSTITUTIONAL AGREEMENT FOR INSTITUTIONAL REVIEW BOARD (IRB) REVIEW

BETWEEN

INSTITUTION RELYING ON THE IRB SERVICES: General Dynamics Information Technology (GDIT)

AND

INSTITUTION SUPPLYING IRB SERVICES: Chesapeake Research Review, Inc.

PART 1
INSTITUTION INFORMATION

This DoD Institutional Agreement for IRB Review describes the responsibilities of the engaged institution and the institution with the IRB. This Agreement, when signed, becomes part of the engaged institution's Federal Assurance for the Protection of Human Research Subjects approved by DoD (and may become part of the Federalwide Assurance (FWA) approved by the Department of Health and Human Services (DHHS)).

A. Engaged Institution Relying on the IRB

Name: General Dynamics Information Technology (GDIT)
DoD Assurance Number (if applicable):
DoD Assurance Expiration (if applicable):
DHHS FWA Number (if applicable): FWA00016277
DoD Addendum to the DHHS FWA Number (if applicable):
DoD Addendum Expiration (if applicable):

B. Institution Supplying the IRB Review Services

Name: Chesapeake Research Review, Inc.
DoD Assurance Number:
DoD Assurance Expiration:
DoD IRB Number* (if applicable):
DHHS FWA Number (if applicable):
DHHS IRB Number* (if applicable): IRB00000790
DoD Addendum to the DHHS FWA Number (if applicable):
DoD Addendum Expiration (if applicable):

*Provide for each IRB that serves as a reviewing IRB and is part of this agreement.

C. Scope

This Agreement applies to the following DoD-supported research conducted by the engaged institution:

[ ] A single DoD-supported research protocol only (list title and other identifying information):

[ ] A group of DoD-supported research protocols (describe here or attach list):

[X] All DoD-supported research performed by this institution.

D. Effective Dates

This Agreement is effective as of the date approved and signed by the DoD Component Designated Official and expires on the date listed in the DoD approval document.

PART 2
INSTITUTIONAL RESPONSIBILITIES

All institutions are responsible for ensuring that their personnel (i.e., the Institutional Official, the IRB, IRB office staff, investigators and research staff, and any other personnel supporting research covered under this Agreement) act in accordance with all applicable federal, state and local laws and regulations (e.g., Title 32 Code of Federal Regulations Part 219 (32 CFR 219); Title 10 United States Code Section 980 (10 USC 980); DoD Directives and Instructions (e.g., DoDI 3216.02); 45 CFR Part 46 (Subparts B, C, and D as made applicable by DoDI 3216.02); DoD Component policies; and the Food and Drug Administration regulations and guidance (e.g., 21 CFR Parts 50, 56, 312, 600, and 812) where applicable in addition to the terms and conditions of the organizations' DoD Assurance and/or their DHHS FWA.

Specific DoD Component requirements are stated in Part 3 of this document.

All institutions will permit, upon request, the inspection of any facilities used in support of the activities described in the "Scope" and other research areas by federal agencies responsible for oversight of human research protection and proper management of the research within the scope of this agreement.

A. The Institutional Official of the Engaged Institution Relying on the IRB will:

1. Ensure that all institutional personnel involved in the research (covered within the scope of this agreement) have completed education and training requirements.

2. Verify that scientific review of the research protocol has been conducted and that the IRB considered the feedback from the scientific review.

3. Verify that the IRB has reviewed the research protocol in accordance with DoD

requirements, including those identified in the research contract or agreement.

4. Ensure institutional personnel comply with requirements and oversight established by the IRB.

5. Ensure institutional personnel follow the approved research protocol.

6. Ensure institutional personnel report to the IRB and DoD: (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 notification.

7. Ensure institutional personnel maintain current copies of the IRB approved research protocol (initial review, continuing review, amendments, adverse event reports, and final report), all communications with the IRB, this Agreement, and other relevant information in accordance with DoD record keeping requirements.

8. Verify the IRB has the expertise and policies and procedures needed to review and oversee the research submitted by the institution (in accordance with 32 CFR 219.107, §.103(b)(3) and (4), and §.115).

B. The Institution Supplying the Reviewing IRB will:

1. Verify that personnel involved in the research have completed required education and training for the protection of human research subjects.

2. Verify that the IRB is properly constituted for reviewing the research.

3. Fulfill the IRB responsibilities identified in the engaged institution's assurance.

4. Provide the Institutional Official of the engaged institution with information about the IRB, such as a list of IRB members or expertise and the written procedures for executing IRB responsibilities in accordance with paragraph A.8 above.

5. Provide to the engaged institution conducting the research and the Principal Investigator(s) a copy of the IRB review and determinations concerning the research (e.g., IRB minutes or other appropriate documents).

6. Maintain current copies of the IRB approved research protocol (initial review, continuing review, amendments, adverse events reports, and final report), all communications with the institution, this Agreement, and other relevant information in accordance with DoD Component record-keeping requirements.

C. Amendments and Termination

1. This Agreement may be modified, cancelled, or renegotiated upon mutual consent, at any time through an amendment signed by authorized representatives of the organizations. A

decision to amend or terminate will be submitted to the DoD Component Designated Oversight Official.

2. The DoD Component Designated Official is not obligated to approve this Agreement.

PART 3
DOD COMPONENT REQUIREMENTS

A. This institution will comply with the requirements of the DoD Component issuing this Agreement. These requirements are identified in Part 3, paragraph B. DoD Components may require that other research, not specifically identified by 32 CFR 219, also comply with the terms of this Agreement (32 CFR 219.101(d)).

B. When this institution conducts research supported by or in collaboration with an organization of another DoD Component, this institution must comply with the policies and procedures of that organization. The requirements of selected DoD Components are identified below:

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
INSTITUTIONAL AGREEMENT

A. Engaged Institution Relying on the External IRB

1. Institutional Signatory Official at the Engaged Institution

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

(b) (6)

Date: 3/20/2012

Rank/Grade:

Telephone Number: (b) (6)

(b) (6)

2. Primary Contact for Human Research Protection at the Engaged Institution

(b) (6)

Date: March 15, 2012

Rank/Grade:

(b) (6)

(b) (6)

B. **Institution with the Reviewing IRB**

1. **Reviewing IRB Chair Agreement**

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

(b) (6)

Date: March 13, 2012

Rank/Grade:
Institutional Title: (b) (6)
Mailing Address: (b) (6)
(b) (6)

For IRBs: Chesapeake IRB
Telephone Number: (b) (6)
FAX Number: (b) (6)

Email Address: (b) (6)

2. **Institutional Official of Institution with the Reviewing IRB**

I am aware that my IRB is entering into this agreement.

Signature: (b) (6)

Date: March 12, 2012

Name: (b) (6)
Rank/Grade:
Institutional Title: (b) (6)
Mailing Address: (b) (6)
(b) (6)

Telephone Number: (b) (6)
FAX Number: (b) (6)

Email Address: (b) (6)

3. **Primary Contact for Human Research Protection at the Institution with the Reviewing IRB**

(b) (6)

Signat

Date: March 12, 2012

Name: (b) (6)
Rank/Grade:
Institutional Title: (b) (6)
Mailing Address: (b) (6)
(b) (6)

Telephone Number: (b) (6)
FAX Number: (b) (6)
Email Address: (b) (6)

Part 4

C. DON HRPP ENDORSEMENT

The Department of the Navy Human Research Protection Program (DON HRPP) has reviewed and, on behalf of the Surgeon General, concurs with this agreement for Chesapeake Research Review, Inc. to provide IRB review and support to General Dynamics Information Technology for all DoD-supported human subject research performed by this institution.

Tracking Number Assigned: DoD-NA3259-IA-IRB-0286

Expiration: 2 September 2013

(b) (6)

[redacted]

27 April 2012