

Subject: None

10/27/2014

To Whom It May Concern:

This is a request under the Freedom of Information Act. I hereby request the following records:

This is a request for the Federal Wide Assurance (FWA) from contract-awardee General Dynamics Corporation approved by the Office of Human Research Protections (OHRP), Dept. of Health and Human Services, in relation to the US Air Force contract BAA-HPW-RHDR-2013-0002, Agency: Department of the Air Force, Office: Air Force Materiel Command, Location: AFRL/RQK - WPAFB; a 7-year contract for Directed Energy Bio-Behavioral Research awarded in 2013, which studies the "human effects" of directed-energy weapons on non-consenting human subjects--essentially, non-consenting American civilians and others.

I also request that, if appropriate, fees be waived as I believe this request is in the public interest. The requested documents will be made available to the general public free of charge as part of the public information service at MuckRock.com, processed by a representative of the news media/press and is made in the process of news gathering and not for commercial usage.

In the event that fees cannot be waived, I would be grateful if you would inform me of the total charges in advance of fulfilling my request. I would prefer the request filled electronically, by e-mail attachment if available or CD-ROM if not.

Thank you in advance for your anticipated cooperation in this matter. I look forward to receiving your response to this request within 20 business days, as the statute requires.

Sincerely,

Ramola Dharmaraj

From: Department of Health and Human Services

11/14/2014

Subject: None

An interim response, stating the request is being processed.



Interim Response

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GENERAL DYNAMICS INFORMATION TECH FAIRFAX VA 49 million contract
Directed Energy Bio-effects Research Program

STATEMENT OF OBJECTIVES

Human Effectiveness Analysis and Integration

Task Order 0004

23 January 2013

V. Statement of Objectives (Task Order 0004):

TITLE: Human Effectiveness Analysis and Integration

This task order effort will be performed on base at Ft. Sam Houston, TX.

Period of Performance: 27 months, 24 months technical effort plus 3 months for Final Technical Report

SECURITY CLASSIFICATION LEVEL: SECRET

1. GOAL:

To support the Human Effects Center of Excellence by performing human effects characterizations, human effects research, modeling and simulation analyses and sensitivity studies, IPT support, consultative support to JNLWD and the Services and aid in strategic planning and construction of human effects research roadmaps.

2. SCOPE:

Support the Human Effects Center of Excellence by characterizing the risk and effectiveness associated with non-lethal weapon employment. This requires a detailed knowledge of non-lethal human effects research, models and the acquisition program landscape allowing HECO to support acquisition IPT's and identify human effects throughout the acquisition process.

3. OBJECTIVES:

To develop an understanding of the bioeffects associated with exposing humans to counter-personnel, non-lethal weapons is essential for legal, treat, policy, and material development purposes. Without it, escalation of force options cannot be provided to war fighters. The objective of this effort is to provide Human Effects data and information that is necessary to characterize devices and technologies intended for this purpose. In order to accomplish these objectives it is essential to conduct laboratory and field experiments necessary to understand a variety of human effects responses across a wide taxonomy of technologies. These include directed energy, riot control agents, broadband light, acoustic sounds, and blunt impact materials. Another objective is to apply that scientific information by engineering optimal effects-based design parameters for non-lethal weapons. Additionally, this effort will provide Integrated Product Teams with engineering data necessary to not only design devices, but to evaluate and test prototypes during material development phases of the DoD acquisition process.

a. Research Description:

An understanding of the bioeffects associated with exposing humans to counter-personnel, non-lethal weapons is essential for legal, treat, policy, and material development purposes. Without it, escalation of force options cannot be provided to warfighters. The objective of this task is to provide Human Effects data and information that is necessary to characterize devices and technologies intended for this purpose. In order to accomplish these objectives it is essential to conduct laboratory and field experiments necessary to understand a variety of human effects responses across a wide taxonomy of technologies. These include directed energy, riot control agents, broadband light, impulse noise, and blunt impact materials. Another objective is to apply that scientific information by engineering optimal effects-based design parameters for non-lethal weapons. Additionally, this task will provide Integrated Product Teams with engineering data necessary to not only design devices, but to evaluate and test prototypes during material development phases of the DoD acquisition process.

The assigned contractors will conduct research to determine appropriate technologies for non-lethal applications and shall conduct and document human effects analyses on candidate Non-Lethal Weapon (NLW) systems, shall conduct and document risk assessments on candidate non-lethal systems, shall develop and or modify models to characterize the physiological and psychological effects of NLW payloads, and support field test planning and data interpretation for NLW.

- i. Toxicology including riot control agents (RCAs), industrial byproducts, combustible materials and their byproducts.
- ii. Blunt Trauma, including dermal penetration and perforation, and non-penetrating insult to soft tissues, organs and skeleton.
- iii. Acoustic/Auditory, Ocular/Visual, Dermal/Haptic, Olfactory including sensory degradation and physiological damage, effects on attention and intent and complete behavior such as decision making and communication.
- iv. Bioelectrics, including modeling current flow through the body, bioeffects on organs, central nervous system (CNS), vascular and neuromuscular and endocrine function.
- v. Interaction between multiple human effects, including modeling physiological effects as a result of multiple application of same NLW, or application of multiple NLWs, modeling of motivational, emotional and cognitive processes as a function of above multiple applications of NLWs.

vi.

4. Other Information.**a. Hazardous Waste.**

The contractor will use hazardous materials in research studies under this effort. Contractors will be required to complete Fort Sam Houston hazardous materials training. All hazardous waste will be disposed of by the government.

b. Human Use.

The contractor will use human subjects in research studies under this effort. The final contract will include the clause entitled "Protection of Human Subjects." For the performance of the contract, the contractor will be complying with the provisions of the following directives/regulations:

- i. Department of Defense, Title 32, Code of Federal Regulations, Part 219 (32 CFR 219), "Protection of Human Subjects" July 2006;
- ii. DHHS Regulations, Title 45, Code of Federal Regulations, Part 46 (45 CFR 46) "Protection of Human Subjects," July 2009;
- iii. DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research," November 2011;
- iv. Air Force Instruction 40-402, "Protection of Human Subjects in Biomedical and Behavioral Research, (May 2005);" and (v) AFRL Instruction 40-402, "Using Human Subjects in Research, Development, Test, and Evaluation" (October 2008).
- v. Contractor personnel performing human use research will be required to take government sponsored initial and annual refreshers "Basic Human Subjects - Biomedical & Social & Behavioral Focus"

Human testing shall not commence until approval from the Air Force IRB has been obtained.

Note: The selected Offeror will be required to establish a Federal Wide Assurance (FWA), for the Protection of Human Subjects, after award if they do not already have a FWA. There is no requirement for offerors to provide evidence of having the FWA with their proposal.

c. Animal Use:

- i. The contractor will use animals in research studies under this effort. The contractor shall comply, as appropriate, with the provisions of the following directives/regulations:
 - (1) Air Force Manual 40-401(I), "The Care and Use of Laboratory Animals in DoD Programs", July 2006;
 - (2) "DoD Instruction 3216.01, "Use of Animals in DoD Programs," September 2010.
- ii. Moreover, the contractor shall maintain records associated with animal subjects research as required by the approved protocol.
- iii. Contractor personnel performing animal use research will be required to take government sponsored initial and annual refreshers training as prescribed by the on-site Veterinarian
- iv. Contractor personnel working with animals are required to have an annual "negative" Tuberculosis (TB) test at the expense of the contractor.

Animal testing shall not commence until approval from the Air Force Institutional Animal Care and Use Committee has been obtained.

5. Deliverables

List of all Deliverables:

- Reports: Status, Technical, Financial, Presentation, and Final
- Hardware: Lab prototype hardware (STE)
- Software: Lab data collection and analysis software

CDRLS: A001, A002, A003, A004, A005, A006, A007, A008 & A009

6. Base Support/Network Access will be provided at JBSA Ft Sam Houston TX for the performance of this effort.