

ORDER FOR SUPPLIES OR SERVICES

PAGE OF PAGES

1 14

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER 08/07/2014		2. CONTRACT NO. (If any) 200-2014-M-60325		6. SHIP TO: a. NAME OF CONSIGNEE NIOSH - MORGANTOWN b. STREET ADDRESS 1095 WILLOWDALE ROAD # 4020 c. CITY MORGANTOWN			
3. ORDER NO. 5. ISSUING OFFICE (Address correspondence to) Ctrs for Disease Control & Prevention PGH Office of Acquisition Services, Branch 4 PO Box 18070, 626 Cochran's Mill Rd Pittsburgh, PA 15236-0070		4. REQUISITION/REFERENCE NO. 000HCCCH-2014-73052		d. STATE WV			
				e. ZIP CODE 26505-2845			
7. TO: a. NAME OF CONTRACTOR RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK		DUNS NUMBER: 038633251		f. SHIP VIA N/A			
b. COMPANY NAME				8. TYPE OF ORDER <input checked="" type="checkbox"/> a. PURCHASE REFERENCE YOUR:			
c. STREET ADDRESS 402 CROFTS HALL				Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.			
d. CITY BUFFALO	e. STATE NY	f. ZIP CODE 14260-0001					
9. ACCOUNTING AND APPROPRIATION DATA 939ZXTM 2555 2014 75-14-0953 5611PH1101		10. REQUISITIONING OFFICE HCCCH					
11. BUSINESS CLASSIFICATION (Check appropriate box(es)) <input type="checkbox"/> a. SMALL <input checked="" type="checkbox"/> b. OTHER THAN SMALL <input type="checkbox"/> c. DISADVANTAGED <input type="checkbox"/> d. WOMEN-OWNED							
12. F.O.B. POINT Destination		14. GOVERNMENT B/L NO. NSS		15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date) 08/17/2015		16. DISCOUNT TERMS Net 30 Days	
13. PLACE OF a. INSPECTION Destination							
17. SCHEDULE (See reverse for Rejections)							
ITEM NO. (a)	SUPPLIES OR SERVICES (b)		QUANTITY ORDERED (c)	UNI T (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	This is a firm fixed price purchase order. To ensure payment, invoice must reference the PO# 200-2014-M-60325, DUNS, and Tax ID Number. Invoice/Payment information: 678-475-4510 Send Invoices to FAX: 404-638-5324 or Email: fmoapinv@cdc.gov Vendor POC: John Violanti Email: violanti@buffalo.edu CDC POC's: Program POC: Tara Hartley PH: 304-285-6222 CS: Kate Oyler PH: 412-386-4450						
SEE BILLING INSTRUCTIONS ON REVERSE	18. SHIPPING POINT		19. GROSS SHIPPING WEIGHT		20. INVOICE NO.		\$101,072.00
	21. MAIL INVOICE TO: a. NAME Centers for Disease Control and Prevention (FMO) b. STREET ADDRESS (or P.O. Box) PO Box 15580 404-718-8100 c. CITY Atlanta						\$101,072.00
					d. STATE GA	e. ZIP CODE 303330080	
22. UNITED STATES OF AMERICA (Signature) ➔				23. NAME (Typed) Lawrence R McCoy			
TITLE: CONTRACTING/ORDERING OFFICER							

SUPPLEMENTAL INVOICING INFORMATION

If desired, this order (or a copy thereof) may be used by the Contractor as the Contractor's invoice, instead of a separate invoice, provided the following statement, (signed and dated) is on (or attached to) the order: "Payment is requested in the amount of \$ _____. No other invoice will be submitted." However, if the Contractor wishes to submit an invoice, the following information must be provided: contract number (if any), order number, item number(s), description of supplies or service, sizes, quantities, unit prices, and extended totals. Prepaid shipping costs will be indicated as a separate item on the invoice. Where shipping costs exceed \$10 (except for parcel post), the billing must be supported by a bill of lading or receipt. When several orders are invoiced to an ordering activity during the same billing period, consolidated periodic billings are encouraged.

RECEIVING REPORT

Quantity in the "Quantity Accepted" column on the face of this order has been inspected, accepted, received by me and conforms to contract. Items listed below have been rejected for the reasons indicated.

SHIPMENT NUMBER	PARTIAL		DATE RECEIVED	SIGNATURE OF AUTHORIZED U.S. GOV'T REP.	DATE
	FINAL				
TOTAL CONTAINERS	GROSS WEIGHT	RECEIVED AT		TITLE	

REPORT OF REJECTIONS

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	Analysis of CVD Markers	1 Each	(b)(4)	

All work is to be performed in accordance with the attached Statement of Work.

The objectives of the project are to:

- 1) identify, retrieve and analyze the frozen blood specimens for the 450 police officers following standardized laboratory protocols,
- 2) perform appropriate quality control measurements, and
- 3) provide the analytic results to NIOSH for incorporation into the BCOPS Study database.

Period of Performance:

August 18, 2014 through August 17, 2015

Quarterly invoices upon showing of completed deliverables

The services contemplated under this contract are considered to be an "Other Function" as defined by the Office of Federal Procurement Policy in OFPP letter 11-01 and by HHS in Acquisition Policy Memorandum 2012-01.

Line(s) Of Accounting:

939ZXTM 2555 2014 75-14-0953

5611PH1101 (b)(4)

STATEMENT OF WORK

Title: Analysis of Three Novel CVD Markers in the BCOPS Study

Background and Need

The services contemplated under this contract are considered to be an “Other Function” as defined by the Office of Federal procurement Policy in OFPP letter 11-01 and by HHS in Acquisition Policy Memorandum 2012-01, per attached statement of work.

Biomarkers have been widely used in epidemiologic research as a way of directly measuring biological processes and understanding disease in its earliest stage. Biomarkers serve as an objective assessment with precise measurement, and strong reliability and validity. In our work with the Buffalo Cardio-metabolic Occupational Police Stress (BCOPS) Study, we have found that police officers have more adverse cardiovascular disease (CVD) risk factor levels compared to the general population and therefore may be at increased risk for developing CVD. Identifying police officers at this early stage is highly desirable in order to reduce or prevent further disease progression.

The BCOPS Study, conducted from 2004-2009 with 464 police officers, is a cross-sectional study exploring the association between work stress and subclinical CVD. As part of the study’s clinical examination, 450 officers provided blood specimens to be frozen for future research purposes. We propose to measure the following biomarkers from frozen serum: homocysteine, neuropeptide Y, and retinol binding protein 4. The purpose of this contract is to have these analyses performed to measure these three biomarkers. This includes the retrieval, proper handling, and analysis of frozen serum specimens collected as part of BCOPS Study.

Homocysteine is a neurotoxic amino acid. Prior research indicates that homocysteine leads to endothelial dysfunction and damage, accelerates thrombin formation and induces vascular smooth muscle proliferation and monocyte chemotaxis, and ultimately increases risk of CVD. Men with post-traumatic stress disorder (PTSD) demonstrated high serum homocysteine levels and this association was related to the duration of the PTSD (52).

Neuropeptide Y (NPY) is an amino acid peptide neurotransmitter and neurohormone that is intimately involved in the body’s stress response. NPY was significantly increased by the acute psychological stress of military interrogation and significantly reduced in individuals 24 hours after stress cessation. Among combat veterans with and without PTSD, trauma exposure rather than PTSD was associated with reduced baseline plasma NPY levels.

Retinol binding protein 4 (RBP4) is an adipokine that appears to be involved in the early phases of insulin resistance and other metabolic syndrome components. Levels of RBP4 have been found to be elevated in individuals with impaired glucose tolerance or type 2 diabetes mellitus. Measurement of these novel biomarkers will permit the examination of associations with 1) police-specific stressors (i.e. shift work, psychological stress) in a known high stress occupational group, and 2) subclinical CVD in a population known to have adverse levels of

CVD risk factors. The information obtained from this study could provide new insights for the association between psychological stress and subclinical CVD.

Project Objectives

The objectives of the project are to:

- 1) identify, retrieve and analyze the frozen blood specimens for the 450 police officers following standardized laboratory protocols,
- 2) perform appropriate quality control measurements, and
- 3) provide the analytic results to NIOSH for incorporation into the BCOPS Study database. Performance of these objectives will allow investigators to assess the following research questions: 1) are occupational stressors associated with these novel biomarkers, and 2) are these biomarkers associated with subclinical CVD?

Scope of Work

(b)(4)

Detailed Technical Requirements

- The University at Buffalo must ensure that confidentiality be maintained and new data must be linked with existing data via the identification number only.
- University at Buffalo laboratory technicians must have obtained at least a high school diploma and must have had prior experience processing laboratory specimens. The University at Buffalo must ensure that quality control analyses be performed on approximately 5% of the blood specimens.

Description of End Product/Deliverables

- Within two months of award, the contractor will have a schedule developed for the identification, retrieval and analysis of frozen specimens.
- Within three months of award, the contractor shall deliver the first progress report with quarterly (6, 9 and 12 months) progress reports thereafter.
- Within four months of the award, the contractor shall notify via email or teleconference to the NIOSH Project Officer that all frozen specimens have been identified and retrieved.
- Within eight months of the award, the contractor shall communicate via email or teleconference with the NIOSH Project Officer to ensure that all blood specimens have been analyzed following standardized laboratory protocols including 5% quality control.
- Within ten months of award, the contractor shall deliver Excel spreadsheets of the results of all analyses. Laboratory results will be reported to the NIOSH Project Officer in an Excel spreadsheet using a standard format and these results will then be entered into the study database. Quality control assessments will be performed and results sent in a similar format. The contractor shall deliver all reports electronically via email to the NIOSH Project Officer. Files and attachments shall be in MS Word or Excel 2009 compatible versions.
- Within 12 months of the award, the contractor will provide a detailed response to any questions from NIOSH about the blood analyte results.
- Within 12 months of the award, a final progress report will be sent to NIOSH. Final financial and progress reports are due on or before contract expiration, documenting and summarizing results of the entire contract work, including recommendations and conclusions.

Reporting Schedule

The contractor will be paid a total of \$101,072 to cover costs associated with identification and retrieval of frozen blood specimens, consultation and oversight, analysis and results of the following biomarkers: homocysteine, neuropeptide Y, and retinol binding protein 4. This total will include the following estimates: \$(b)(5) for identification and retrieval of frozen specimens, \$(b)(5) for consultation and oversight, and \$(b)(5) for analysis of frozen specimens. Payments will be made monthly or quarterly based on receipt of invoices sent to NIOSH that indicate the number of laboratory analyses completed.

Period of performance: August 18, 2014 – August 17, 2015.

The contractor will report on progress quarterly by sending a brief report indicating the number of analyses completed and a description of finished deliverables. Deliverables that have been partially completed during the quarter being invoiced will be briefly reported by the contractor in writing. When these documents are received by the NIOSH Project Officer then invoices will be approved.

Deliverables

Item	Description	Delivery Schedule	Recipient
1	Schedule Development	Within 2 nd month	Project Office
2	Identification and retrieval of frozen specimens	Within 4 th month	
3	Laboratory analyses, quality control analyses performed	Within 8 th month	
4	Biomarker data transmitted	Within 10 th month	Project Office
5	Response to any NIOSH inquiries about analyte results transmitted	Within 12 th month	Project Office
6	Three Progress reports – via email	Every Quarter	Project Office
7	Final Report – via email	End of Contract	Contract Office & Project Office

TERMS AND CONDITIONS

FAR SOURCE	TITLE AND DATE
52.204-13	System for Award Management Maintenance (July 2013)
52.212-4	Contract Terms and Conditions- Commercial Items (May 2014)
52.232-40	Providing Accelerated Payments to Small Business Contractors (Dec 2013)
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations (Jan 2010)
352.239-70	Standard for Security Configurations (Jan 2010)
352.239-71	Standard for Encryption Language (Jan 2010)
352.239-72	Security Requirements for Federal Information Technology Requirements (Jan 2010)
352.239-73	Electronic and Information Technology Accessibility (Jan 2010)

FAR 52.252-2 --CLAUSES INCORPORATED BY REFERENCE (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. **Also, the full text of a clause may be accessed electronically at this/these address(es):**

Regulations URLs: (Click on the appropriate regulation.)

<http://farsite.hill.af.mil/reghtml/regs/far2afmcgars/fardfars/far/far1toc.htm>

<http://www.hhs.gov/policies/hhsar/subpart301-1.html>

NOTE: After selecting the appropriate regulation above, at the “table of Contents” page, conduct a search for the desired regulation reference using your browser’s FIND function. When located, click on the **regulation reference** (hyperlink).

FAR 52.212-5 -- Contract Terms and Conditions Required to Implement Statutes or Executive Orders -- Commercial Items (May 2014)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

- (1) 52.222-50, Combating Trafficking in Persons (FEB 2009) (22 U.S.C. 7104(g)).
 - ____ Alternate I (AUG 2007) of 52.222-50 (22 U.S.C. 7104(g)).
- (2) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C. 3553).
- (3) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Public Laws 108-77, 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the contracting officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

- ____ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).
- ____ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (Apr 2010) (41 U.S.C. 3509).
- ____ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub L. 111-5) (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009).
- X** (4) 52.204-10, Reporting Executive compensation and First-Tier Subcontract Awards (Jul 2013) (Pub. L. 109-282) (31 U.S.C. 6101 note).
- ____ (5) [Reserved]
- ____ (6) 52.204-14, Service Contract Reporting Requirements (Jan 2014) (Pub. L. 111-117, section 743 of Div. C).
- ____ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Jan 2014) (Pub. L. 111-117, section 743 of Div. C).
- X** (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Aug 2013) (31 U.S.C. 6101 note).
- ____ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Jul 2013) (41 U.S.C. 2313).
- ____ (10) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (May 2012) (section 738 of Division C of Public Law 112-74, section 740 of Division C of Pub. L. 111-117, section 743 of Division D of Pub. L. 111-8, and section 745 of Division D of Pub. L. 110-161).
- ____ (11) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (Nov 2011) (15 U.S.C. 657a).
- ____ (12) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Jan 2011) (if the offeror elects to waive the preference, it shall so indicate in its offer)(15 U.S.C. 657a).
- ____ (13) [Reserved]
- ____ (14) (i) 52.219-6, Notice of Total Small Business Aside (Nov 2011) (15 U.S.C. 644).
 - ____ (ii) Alternate I (Nov 2011).
 - ____ (iii) Alternate II (Nov 2011).
- ____ (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644).

- ____ (ii) Alternate I (Oct 1995) of 52.219-7.
- ____ (iii) Alternate II (Mar 2004) of 52.219-7.
- ____ (16) 52.219-8, Utilization of Small Business Concerns (May 2014) (15 U.S.C. 637(d)(2) and (3)).
- ____ (17) (i) 52.219-9, Small Business Subcontracting Plan (Jul 2013) (15 U.S.C. 637 (d)(4)).
 - ____ (ii) Alternate I (Oct 2001) of 52.219-9.
 - ____ (iii) Alternate II (Oct 2001) of 52.219-9.
 - ____ (iv) Alternate III (July 2010) of 52.219-9.
- ____ (18) 52.219-13, Notice of Set-Aside of Orders (Nov 2011) (15 U.S.C. 644(r)).
- ____ (19) 52.219-14, Limitations on Subcontracting (Nov 2011) (15 U.S.C. 637(a)(14)).
- ____ (20) 52.219-16, Liquidated Damages—Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
- ____ (21) (i) 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (Oct 2008) (10 U.S.C. 2323) (if the offeror elects to waive the adjustment, it shall so indicate in its offer).
 - ____ (ii) Alternate I (June 2003) of 52.219-23.
- ____ (22) 52.219-25, Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting (Jul 2013) (Pub. L. 103-355, section 7102, and 10 U.S.C. 2323).
- ____ (23) 52.219-26, Small Disadvantaged Business Participation Program—Incentive Subcontracting (Oct 2000) (Pub. L. 103-355, section 7102, and 10 U.S.C. 2323).
- ____ (24) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Nov 2011) (15 U.S.C. 657f).
- ____ (25) 52.219-28, Post Award Small Business Program Rerepresentation (Jul 2013) (15 U.S.C. 632(a)(2)).**
- ____ (26) 52.219-29, Notice of Set-Aside for Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (Jul 2013) (15 U.S.C. 637(m)).
- ____ (27) 52.219-30, Notice of Set-Aside for Women-Owned Small Business (WOSB) Concerns Eligible Under the WOSB Program (Jul 2013) (15 U.S.C. 637(m)).
- ____ (28) 52.222-3, Convict Labor (June 2003) (E.O. 11755).**
- ____ (29) 52.222-19, Child Labor—Cooperation with Authorities and Remedies (Jan 2014) (E.O. 13126).**
- ____ (30) 52.222-21, Prohibition of Segregated Facilities (Feb 1999).**
- ____ (31) 52.222-26, Equal Opportunity (Mar 2007) (E.O. 11246).**
- ____ (32) 52.222-35, Equal Opportunity for Veterans (Sep 2010) (38 U.S.C. 4212).**
- ____ (33) 52.222-36, Affirmative Action for Workers with Disabilities (Oct 2010) (29 U.S.C. 793).**
- ____ (34) 52.222-37, Employment Reports on Veterans (Sep 2010) (38 U.S.C. 4212).**
- ____ (35) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).

- ____ (36) 52.222-54, Employment Eligibility Verification (Aug 2013). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)
- ____ (37) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
 - ____ (ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- ____ (38) 52.223-15, Energy Efficiency in Energy-Consuming Products (Dec 2007) (42 U.S.C. 8259b).
- ____ (39) (i) 52.223-16, IEEE 1680 Standard for the Environmental Assessment of Personal Computer Products (Dec 2007) (E.O. 13423).
 - ____ (ii) Alternate I (Dec 2007) of 52.223-16.
- ____ (40) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging while Driving (Aug 2011).**
- ____ (41) 52.225-1, Buy American--Supplies (May 2014) (41 U.S.C. chapter 83).
 - ____ (42) (i) 52.225-3, Buy American--Free Trade Agreements--Israeli Trade Act (May 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43).
 - ____ (ii) Alternate I (May 2014) of 52.225-3.
 - ____ (iii) Alternate II (May 2014) of 52.225-3.
 - ____ (iv) Alternate III (May 2014) of 52.225-3.
 - ____ (43) 52.225-5, Trade Agreements (Nov 2013) (19 U.S.C. 2501, *et seq.*, 19 U.S.C. 3301 note).
- ____ (44) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).**
- ____ (45) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2303 Note).
- ____ (46) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).
- ____ (47) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).
- ____ (48) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505), 10 U.S.C. 2307(f).
- ____ (49) 52.232-30, Installment Payments for Commercial Items (Oct 1995) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
- ____ (50) 52.232-33, Payment by Electronic Funds Transfer— System for Award Management (Jul 2013) (31 U.S.C. 3332).**
- ____ (51) 52.232-34, Payment by Electronic Funds Transfer—Other Than System for Award Management (Jul 2013) (31 U.S.C. 3332).

- ____ (52) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).
- ____ (53) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
- ____ (54) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631).
 - ____ (ii) Alternate I (Apr 2003) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

- ____ (1) 52.222-41, Service Contract Labor Standards (May 2014) (41 U.S.C. chapter 67.).
- ____ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
- ____ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards -- Price Adjustment (Multiple Year and Option Contracts) (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
- ____ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards -- Price Adjustment (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
- ____ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (May 2014) (41 U.S.C. chapter 67).
- X** (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (May 2014) (41 U.S.C. chapter 67).
- ____ (7) 52.222-17, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495).
- ____ (8) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (May 2014) (42 U.S.C. 1792).
- ____ (9) 52.237-11, Accepting and Dispensing of \$1 Coin (Sep 2008) (31 U.S.C. 5112(p)(1)).

(d) *Comptroller General Examination of Record* The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records -- Negotiation.

- (1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.
- (2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.
- (3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or

maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)

(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c) and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—

- (i) 52.203-13, Contractor Code of Business Ethics and Conduct (Apr 2010) (41 U.S.C. 3509).
- (ii) 52.219-8, Utilization of Small Business Concerns (May 2014) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$650,000 (\$1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
- (iii) 52.222-17, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (1) of FAR clause 52.222-17.
- (iv) 52.222-26, Equal Opportunity (Mar 2007) (E.O. 11246).
- (v) 52.222-35, Equal Opportunity for Veterans (Sep 2010) (38 U.S.C. 4212).
- (vi) 52.222-36, Affirmative Action for Workers with Disabilities (Oct 2010) (29 U.S.C. 793).
- (vii) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
- (viii) 52.222-41, Service Contract Labor Standards (May 2014), (41 U.S.C. chapter 67).
- (ix) 52.222-50, Combating Trafficking in Persons (Feb 2009) (22 U.S.C. 7104(g)).
 - ____ Alternate I (Aug 2007) of 52.222-50 (22 U.S.C. 7104(g)).
- (x) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (May 2014) (41 U.S.C. chapter 67.)
- (xi) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (May 2014) (41 U.S.C. chapter 67)
- (xii) 52.222-54, Employment Eligibility Verification (Aug 2013).
- (xiii) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
- (xiv) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (May 2014) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
- (xv) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of Clause)

CDC100.0001 Needle Exchange (Jan 2014)

No funds appropriated in the FY14 Appropriations Act and obligated to this contract may be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

(End of clause)

CDC0.G007 Contracting Officer (Jul 1999)

(a) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.

(b) No information, other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

(End of Clause)

CDC37.0001 Non-Personal Services (April 2013)

(a) Personal services shall not be performed under this contract. Although the Government may provide sporadic or occasional instructions within the scope of the contract, the Contractor is responsible for control and supervision of its employees. If the Contractor (including its employees) believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

(b) The contractor shall comply with, and ensure their employees and subcontractors comply with, CDC Policy titled "Identification of Contractors' Employees and Safeguarding Government Information." No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. . The contractor is limited to performing the services identified in the contract statement of work and shall not interpret any communication with anyone as a permissible change in contract scope or as authorization to perform work not described in the contract. All contract changes will be incorporated by a modification signed by the Contracting Officer.

(c) The Contractor shall ensure that all of its employees and subcontractor employees working on this contract are informed of the substance of this clause. The Contractor agrees that this is a non-personal services contract; and that for all the purposes of the contract, the Contractor is not, nor shall it hold itself out to be an agent or partner of, or joint venture with, the Government. The Contractor shall notify its employees that they shall neither supervise nor accept supervision from Government employees. The substance of this clause shall be included in all subcontracts at any tier.

(d) Nothing in this clause shall limit the Government's rights in any way under any other provision of the contract, including those related to the Government's right to inspect and accept or reject the services performed under this contract.

(End of Clause)

CDCAG001 – Invoice Submission (Mar 2006)

- (a) The Contractor shall submit the original contract invoice/voucher to the address shown below:

Mail:
CDC Office of the Chief Financial Officer
P.O. Box 15580
Atlanta, Ga. 30333

Or – The Contractor may submit the original invoice/voucher via facsimile or email:

Fax: 404-638-5324
Email: FMOAPINV@CDC.GOV

NOTE: Submit to only one (1) of the above locations.

- (b) The contractor shall submit one (1) copy of the invoice/voucher to the cognizant contracting office previously identified in this contract. These invoices/voucher copies shall be addressed to the attention of the Contracting Officer.
- (c) The Contractor is , is not required to submit a copy of each invoice directly to the Project Officer concurrently with submission to the Contracting Officer.
- (d) In accordance with 5 CFR part 1315 (Prompt Payment), CDC's Financial Management Office is the designated billing office for the purpose of determining the payment due date under FAR 32.904.
- (e) The Contractor shall include (as a minimum) the following information on each invoice:
- (1) Contractor's Name & Address
 - (2) Contractor's Tax Identification Number (TIN)
 - (3) Purchase Order/Contract Number and Task Order Number, if Appropriate
 - (4) Invoice Number
 - (5) Invoice Date
 - (6) Contract Line Item Number and Description of Item
 - (7) Quantity
 - (8) Unit Price & Extended Amount for each line item
 - (9) Shipping and Payment Terms
 - (10) Total Amount of Invoice
 - (11) Name, title and telephone number of person to be notified in the event of a defective invoice
 - (12) Payment Address, if different from the information in (c)(1).
 - (13) DUNS + 4 Number

(End of Clause)

SOLICITATION, OFFER AND AWARD		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)			<input checked="" type="checkbox"/>	RATING		PAGE 1	OF PAGES 40
2. CONTRACT NO. 200-2003-01580	3. SOLICITATION NO. 2003-N-00764	4. TYPE OF SOLICITATION <input type="checkbox"/> SEALED BID (IFB) <input checked="" type="checkbox"/> NEGOTIATED (RFP)	5. DATE ISSUED	6. REQUISITION/PURCHASE NO. 1267					
7. ISSUED BY Centers for Disease Control and Prevention Acquisition and Assistance Field Branch PO Box 18070, 626 Cochran's Mill Rd Pittsburgh, PA 15236-0070	CODE 436	8. ADDRESS OFFER TO (If other than Item 7)			Approved as to Form and Legality:				

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder."

SOLICITATION

9. Sealed offers in original and _____ copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in _____ until _____ local time _____ (Hour) _____ (Date)

CAUTION -- LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL: <input checked="" type="checkbox"/>	A. NAME Florence P. Black	B. TELEPHONE (NO COLLECT CALLS) AREA CODE NUMBER: EXT: (412) 386-4451	C. E-MAIL ADDRESS fbb4@cdc.gov
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(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)		
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X	F	DELIVERIES OR PERFORMANCE	25		EVALUATION FACTORS FOR AWARD				
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OFFER (Must be fully completed by offeror)

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within _____ calendar days (60 calendar days unless a different period is inserted by the offeror) from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT <input checked="" type="checkbox"/> (See Section I, Clause No. 52-232-8)	10 CALENDAR DAYS %	20 CALENDAR DAYS %	30 CALENDAR DAYS %	CALENDAR DAYS %
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14. ACKNOWLEDGMENT OF AMENDMENTS (The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated: _____)	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE
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15A. NAME AND ADDRESS OF OFFEROR	CODE 2741	FACILITY	16. NAME AND ADDRESS OF PERSON AUTHORIZED TO SIGN OFFER (Type or Print)		
Research Foundation of SUNY 520 Lee Entrance Suite 211 UB Commons Amherst, NY 14228-					

15B. TELEPHONE NO. AREA CODE NUMBER EXT.	15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE. <input type="checkbox"/>	17. SIGNATURE	18. OFFER DATE
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AWARD (To be completed by Government)

19. ACCEPTED AS TO ITEMS NUMBERED See Section B	20. AMOUNT \$1,724,651.00	21. ACCOUNTING AND APPROPRIATION 92101CZ 2555 2003 75 3 0943 11B18 \$375,000.00
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22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304(c)() <input type="checkbox"/> 41 U.S.C. 253(c)()	23. SUBMIT INVOICES TO ADDRESS SHOWN IN (4 copies unless otherwise specified) <input checked="" type="checkbox"/>	ITEM Block 7
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24. ADMINISTERED BY (If other than Item 7) Centers for Disease Control and Prevention Acquisition and Assistance Field Branch PO Box 18070, 626 Cochran's Mill Rd Pittsburgh, PA 15236-0070	25. PAYMENT WILL BE MADE BY CODE 434
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26. NAME OF CONTRACTING OFFICER (Type or print) Larry E. Guess	27. UNITED STATES OF AMERICA (Signature of Contracting Officer)	28. AWARD DATE
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IMPORTANT -- Award will be made on this form, or on Standard Form 26, or by other authorized official written notice.

Section B - Supplies Or Services and Prices/Costs

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	Research on Police Stress Study of Stress Biomarkers with Metabolic and Vascular Consequences in Police Officers ("Police Stress Study") in accordance with the Statement of Work in Section C.	1 Job	(b)(4)	

B.1 HHSAR 352.232-74 Consideration -- Estimated Cost (Apr 1984)

- (a) It is estimated that the total cost to the Government for full performance of this contract will be \$1,724,651.00.
- (b) Total funds currently available for payment and allotted to this contract are \$375,000.00. For further provisions on funding, see the Limitation of Funds, FAR 52.232.22.
- (c) It is estimated that the amount currently allotted will cover performance of Task 2.b. I-iv for the first 100 participant examinations which is anticipated to be completed 10 months after the work begins.
- (d) The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

Section C - Description/Specification/Work Statement

1) Work Statement with Project Background

a) Background

i) General Description of Required Objectives and Desired Results

The Health Effects Laboratory Division, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC) proposes to initiate a baseline observational research study of police officers. The study will focus on thorough measurements of 1) physiological stress and 2) subclinical morbidities underlying the insulin resistance and coronary syndromes as well as subclinical vascular abnormalities. It will take practical advantage of an already established and rigorously documented cohort by an organization which 1) will take the lead in assessing the psychosocial characteristics of stress within the cohort, and 2) has demonstrated capacity for future longitudinal studies. The initiative will address 9 of 28 Focus Areas and 5 of 10 Leading Health Indicators of the United States Department of Health and Human Service's Healthy People 2010.[1-3] The specific objectives of the study are:

- In a demographically defined cohort of police officers, to characterize the nature of patterns and distribution of those patterns of 1) physiological measures related to chronic stress and 2) physiological, biochemical, and anthropometric measures of subclinical morbidity associated with chronic metabolic and cardiovascular diseases.
- To describe the nature of interrelations among 1) the aforementioned physiological measures of chronic stress, 2) the attendant measures of subclinical morbidity, and 3) psychosocial measurements characteristic of the cohort derived independently of the contract and for which the contractor will take independent leadership.
- To position the study to take advantage of potential longitudinal and/or event follow-up studies to be supported by mechanisms unrelated to this contract.

ii) Background Information Leading to a Clear Understanding of the Requirements and How They Evolved

“Stress” is a broadly applied but loosely defined term. Often used as a well-defined measure with precise definition, it is not. “Stress” can be broadly defined as disturbance in homeostasis.[4-6] Maintaining homeostasis in the face of internal or external challenges, called stressors, requires constant adjustments of hormones, autonomic function, and behaviors. The resulting neuroendocrine adaptations are the “stress response.” These are influenced by individual perception and ability to control the stressor. Maintaining stability through adaptive change in response to stressors (allostasis) leads to the concept of “allostatic load.” Allostatic load is the wear-and-tear the body experiences from repeated cycles of allostasis, especially, “when adaptation efforts are excessive ... in terms of frequency, duration, or extent.”[4]

(1) Job and Lifestyle Characteristics

Job characteristics such as autonomy, workload pressure, and supervisory practices are notable risk factors for stress perception, musculoskeletal and psychological disorders, and cardiovascular disease.[7-9] Certain aspects of work (e.g., high demand/low control, shift work, frequent public contact) are considered to be highly stressful.[10,11] Neuroendocrine reactions to such stressors provide the means necessary to respond. Accordingly, neuroendocrine reactivity, including catecholamine and cortisol release, is a necessary concomitant of stress.[12] Continued and

excessive neuroendocrine activation resulting from continued, threatening, and ambiguous job demands characterizes “allostatic load.”[5]

Because of its very nature, law enforcement is stressful. In order to defuse violent confrontations threatening human safety, police officers are uniquely and consistently placed in stressful circumstances—resisting the natural response to “fight or flee.” Because of their role in society police officers are frequently marginalized and underserved.[13-16] They are at increased risk for posttraumatic stress disorder,[17,18] maladaptive coping behaviors (e.g., alcoholism),[14,15] and cardiovascular disease;[19-22] and, they die at a younger age.[23] Thus, police officers are an appropriate population to study “stress” and associated subclinical morbidities leading to illness and disease.

Participation by police officers in establishing the evidence for integration of relations among components of this allostasis stress model can lead to subsequent studies of occupational cohorts in whom stressors may be less evocative of allostatic load and correlate morbidities. Such evidence will lead to intervention strategies founded on more objective criteria and thereby benefit not only underserved and misunderstood occupational sectors, but also create a more efficient and appropriate strategy for interventions that will follow.[16]

(2) Neuroendocrine and Subclinical Morbidity Considerations

The neuroendocrine activation of the hypothalamic-pituitary-adrenal (HPA) axis is a critical component in the response to stressors because it is a mediator of allostasis.[5,12] Following disruption of homeostasis the axis is activated. It meets stressor demands through the synthesis and/or release of several hormones—corticotropin-releasing hormone (CRH), arginine vasopressin (AVP), adrenocorticotropin hormone (ACTH), and cortisol. The coordinated actions of CRF and ACTH release cortisol into the circulation, which functions as the effector in this system. Thus, cortisol response is a measure of the “health” of the HPA axis. Indeed, it is variation of cortisol in response to standardized challenges of the HPA axis that correlates with various measures of allostatic load,[24-26] *not* a casual blood or saliva measurement.[27] However, other hormones of this axis can be utilized to determine dysfunction as well.[28]

Activation of the HPA axis and sympathetic nervous system activation leads to concomitant effects on 1) carbohydrate and lipid metabolism, and 2) vasomotor activity.[29] The consequence of continued and excessive activation leads to the allostatic load. The subclinical morbidities found in the insulin resistance syndrome (hypertension, dyslipidemia, glucose intolerance),[30-35] the coronary syndromes (atherosclerosis, hemostasis and thrombosis derangements, inflammation),[36] and subclinical vascular abnormalities (orthostatic hypotension, loss of heart rate variability, endothelial dysfunction)[37-39] are a consequence of the allostatic load. Allostatic load presages subclinical morbidity, leading to clinical disease. In particular, the insulin resistance syndrome has been recognized as an important component in the etiology of clinical diabetes and contributory to cardiovascular disease[22,40,41]—conditions noted in police officers.[22,23]

Correlate with pathophysiological evolution of stress-mediated disease is psychosocial evolution of stress-mediated mental dysfunction. Activation of cognitive and emotional states by heightened alertness, vigilance, and a variety of other psychological mechanisms is a normal allostatic response. With prolonged and excessive activation maladaptive coping behaviors manifest (e.g., alcoholism), and ultimately serious mental illnesses ensue, such as depression—even leading to suicide.[42] Perturbations in HPA axis function have been implicated in the evolution of such psychological dysfunction.[28,43-46]

(3) Summary and Research Objectives

This allostasis model of stress-mediated disease and mental dysfunction begins with normative physiological and psychological responses to stressors. Continued and excessive activation portends sequelae—high allostatic load—leading to a spiraling and self-reinforcing evolution of maladaptive behaviors and pathophysiological conditions characterized by eating disorders, decreased physical fitness, anxiety, obesity, substance abuse—especially alcoholism, depression, lipid and carbohydrate metabolic derangements, hypertension, atherosclerotic disease, type 2 diabetes, and eventually irreversible clinical disease.[27,30,47-63]

Having specifically demonstrated that perturbations in HPA axis function are implicated in the evolution of chronic disease and mental dysfunction, three key research objectives emerge:

- What are the nature and distribution of patterns of measurement of 1) physiological stress and 2) subclinical morbidities in an occupational cohort subject to high levels of stress?

Although clinical studies and one general population observational study[30] have described general patterns of response of HPA function to perturbation in a variety of groups with morbid conditions, these descriptions have not systematically described how dose-response features are distributed in demographically defined populations at high risk, nor have they attempted to examine other axes associated with response to physiological stress, such as the sympathetic nervous system. Similar issues can be raised for well-established measures of subclinical morbidity reflected in the insulin resistance and coronary syndromes as well as subclinical vascular abnormalities.

- How are the patterns of measures of physiological stress jointly related to patterns characterizing the aforementioned subclinical morbidities as well as occupationally mediated patterns of psychological dysfunction and of social organization?

These interrelations have not been systematically characterized in a well defined high-risk population. Such integration is necessary to address the nature and consequences of occupational mediated stress, particularly that associated with police work. Even in clinical laboratory and general population studies, no study has attempted to provide such a high degree of integration. While the emphasis of this contract proposal is on physiological and subclinical medical morbidity, the capacity to extend this systematic characterization to include psychosocial constructs represents a key feature contributing to efficiencies and ultimately practical and effective intervention strategies. In conjunction with the operational and conceptual capabilities needed to address measurements of physiological stress and of subclinical medical morbidities, the capacity of the contractor to bring to the research program demonstrated and established leadership as well as operational experience in the characterization of psychological function and social organization of police cohorts provides for a highly integrated effort that is expected to bring an unprecedented level of coordination among the major scientific disciplines involved in stress research.

- Given the aforementioned goal to achieve a high degree of integration across conceptual domains and scientific disciplines, how can the contractor and the government position the research effort to address future scientific questions about the role of stress in police work that will involve longitudinal and follow-up designs to be funded by mechanisms outside and beyond this contract proposal?

Parallel assessments of “stress” in separate conceptual domains and scientific disciplines have been deficient, and thus has hindered stress research. This deficiency has lead to a lack of integration, predictive validity, and successful intervention strategies. Demonstrated and successful achievement of such integration by activities extending from the effort supported by the proposed contract will serve future opportunities in stress research that lead to longitudinal predictions of morbidities and intervention effectiveness. A key aspect of the proposal is to position the effort to be able to efficiently and effectively address such a future by logical extensions of the effort itself.

b) Work Statement

i) Introduction

This initiative proposes to examine the central role of HPA axis perturbation as the integrative marker of psychosocial and physiological stress leading to subclinical morbidities characteristic of the insulin resistance and coronary syndromes as well as subclinical vascular abnormalities.

In particular, measurements of components of the allostasis stress model and subclinical morbidity would include but not necessarily be limited to 1) HPA axis function; 2) amount and location of body fat measured by dual energy

X-ray absorptiometry (DEXA); 3) non-invasive assessments of vascular abnormalities, including atherosclerosis (e.g., intima media thickness by carotid ultrasound), endothelial dysfunction (e.g., brachial reactivity), and autonomic function (e.g., orthostatic hypotension, heart rate variability); and 4) clinical and laboratory assessments of blood pressure; total, HDL, and LDL cholesterol; HgbA1C; and fasting triglyceride, glucose, and insulin levels.

Within the limits of available funding, offerors submitting a proposal are encouraged to consider additional, alternate, or exclusion of measures appropriate to the design features and the three key research objectives of the study. Such suggestions should be preceded by conceptual justifications in the context of the proposed allostasis stress model. For example, logically appropriate assessment of the role of sympathetic nervous system function may significantly contribute unique understanding of another facet of this allostasis model of stress. Similar considerations of laboratory tests derived from blood specimens related to immune function, hemostasis/thrombosis, and chronic inflammatory processes may be appropriate.

The initiative is best served by developing the initial study in an established cohort at the highest risk for the consequences of chronic stress. Evidence suggests police officers are at such risk. A well characterized cohort in whom workplace stressors as well as individual psychosocial characteristics have already been assessed will allow the initiative to efficiently and effectively target and integrate measurements of physiological and subclinical morbidities as the primary research goal.

Police departments are closed hierarchical communities, and police officers are both admired and disparaged by various members of society. Their willingness to participate in such research critically hinges on access to their community through authority structures which they respect and to which they will respond. A critical component to the success of this study will be the involvement of investigators possessing documented evidence of 1) successfully integrated research activities measuring psychosocial and physiological stress as well as the aforementioned subclinical morbidities, and 2) established credibility of scientific research in the police community.

ii) Study Design

This is an observational study focused on a defined cohort of suburban and/or urban police officers. Between 800 and 1,000 officers will be recruited from a demographically defined population of police officers in which 1) significant proportions (preferred minimum of 20%) of the cohort will represent women as well as men ; 2) at least two racial/ethnic groups; , and 3) a documented natural range of ages for active, as opposed to retired, police officers representative of the population cohort.

The fundamental design of this study is a statistically rigorous cross-sectional survey derived from a demographically defined population of police officers. The sampling frame should consist of a complete and thorough list of all sworn police officers from one police department consisting of 800 or more officers. Restricting the study sample to one large police department is intended to reduce potential variability caused by different administrative structures. A representative sample may reflect 100% of the study sample depending upon the size of the proposed police department population, or it may follow a sampling strategy that is conceptually justified and operationally tractable. The aforementioned representation requirements of sex, ethnicity, and age must be addressed in whatever strategy is proposed.

iii) Operational Components

The study will establish a formal Steering Committee comprised of the Principle Investigator, two other contractor representatives described as key personnel, the NIOSH Project Officer (PO) and NIOSH staff designated by the PO. The Steering Committee will establish all subsequent subcommittees comprised of contract and NIOSH investigators, establish the mandates of those subcommittees, and act as the focal point for contract performance.

Upon award of the contract, the first six months will be devoted to developing protocols, obtaining OMB clearance if needed, piloting, and revising protocols. Beginning at month 6 recruitment and examinations will begin, continuing for three years. Planning of data analysis and manuscripts will start at the beginning of year 4. During the course of the study, at least three major papers, one of which will be a description of the study design, will be written and submitted for publication by the end of the contract. Close out activities will begin during the last year,

with the total contract period lasting 4 years. Additional components are summarized in the time line of Figure 1 and in Tables 1 and 2.

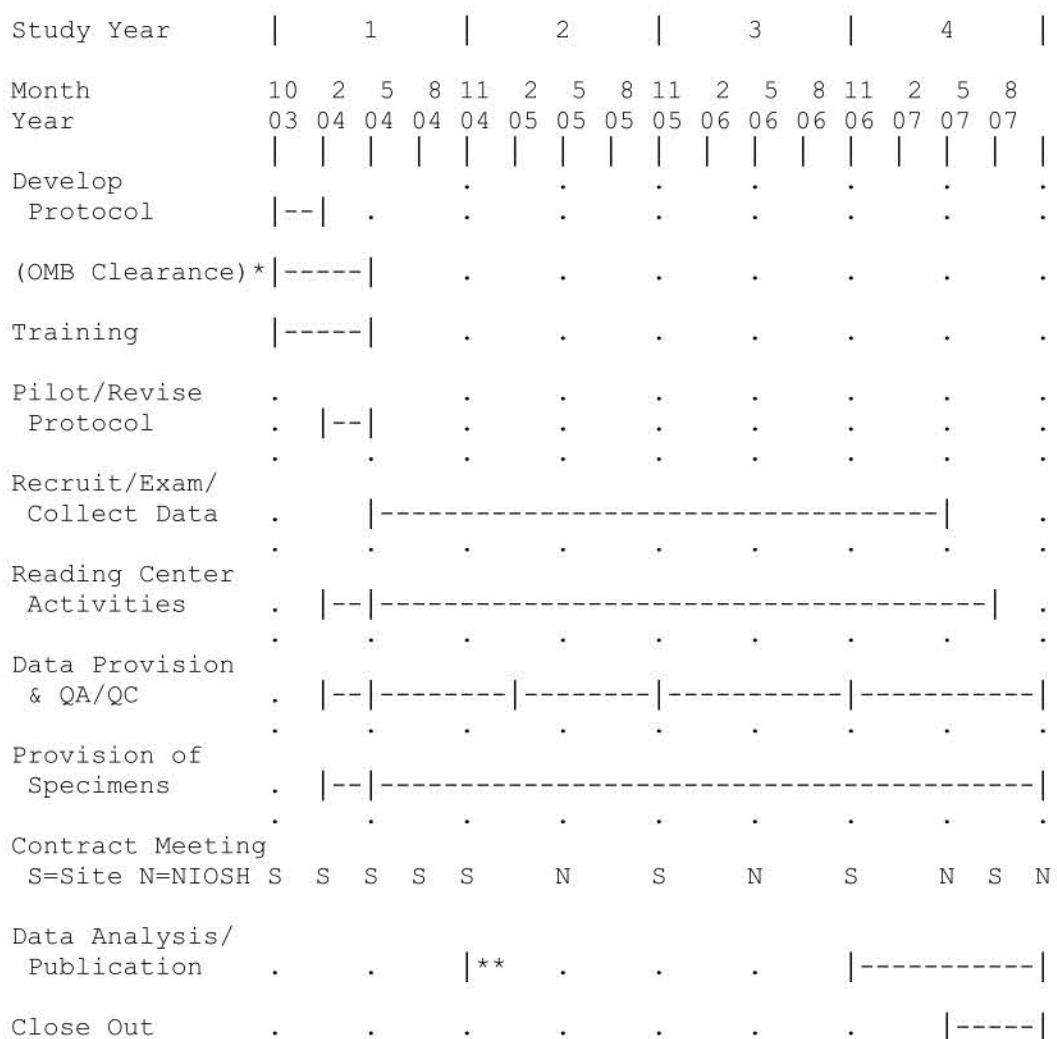
It is anticipated that the award would be made in late summer of 2003. For the purposes of planning, the time line identifies time periods based on a start date of October 1, 2003, although the actual start date may differ.

Table 1: Designated Study Years

Study Year	Calendar Date
1	1 Oct 2003 — 30 Sept 2004
2	1 Oct 2004 — 30 Sept 2005
3	1 Oct 2005 — 30 Sept 2006
4	1 Oct 2006 — 30 Sept 2007

iv) Time Line

Figure 1: Time Line for Police Stress Study



*Only if required

**Design paper

Table 2: Time Line for Police Stress Study (assumes a start date of November 1, 2003)

Activity	Time Period (Month)	Comment
Develop Protocol	0 - 3	
Training (OMB Clearance)	0 - 6	OMB clearance may not be required
Pilot Study and Revise Protocol	3 - 6	
Recruitment, Examination, and Data Collection	6 - 42	Consider feasibility of earlier completion
Reading Center Activities	3 - 45	Includes 3 months before beginning and after ending of Examinations
Data & Specimen Provision, QA & QC	3 - 48	Ongoing QA & QC and specimen provision, change to annual data provision at beginning of year 3 (see Fig 1)
Contractor Meetings	0 - 48	Onsite quarterly meetings 1 st year, every 6 months thereafter (see Fig 1)
Data Analysis and Publications	12 & 36 - 48	Complete design paper at end of first year
Close Out	42 - 48	

v) Examination Components

Data to be collected by this contract is approximated by the following list of components, which may be modified during protocol development:

- (1) Personal identification information (Name, contact information, follow-up information)
- (2) Demographic information (ethnicity, sex, age, occupational position, etc.). As feasible, this information should also be obtained on people who decline to participate.
- (3) Anthropometry (height, weight, waist and hip circumferences, abdominal height) and clinical examination measures (casual blood pressures, resting pulse, EKG)
- (4) Dual energy X-ray absorptiometry (DEXA) measurements of amount and location of body fat, muscle mass, and bone mass.
- (5) Non-invasive assessments of vascular abnormalities, including,
 - (a) atherosclerosis (e.g., intima media thickness by carotid ultrasound),
 - (b) endothelial dysfunction (e.g., brachial reactivity), and
 - (c) autonomic function (e.g., orthostatic hypotension, heart rate variability)

- (6) Appropriate fasting whole blood, white cell buffy coat, serum, plasma, and special tissue specimens for the laboratory evaluation of total, HDL, and LDL cholesterol; fasting triglycerides, glucose, insulin levels; Hgb1AC; C-reactive protein, fibrinogen; and DNA. Appropriate laboratory tests derived from blood specimens related to immune function, hemostasis/thrombosis, and chronic inflammatory processes may be considered.
- (7) Multiple saliva specimens on individuals at timings concordant with established provocation protocols for measuring HPA axis function (e.g., cortisol). This assessment will be in collaboration with NIOSH investigators who will provide laboratory support and resources specific to this assessment.

For planning purposes, consider aspects of the examination and data collection effort that could lead to significant cost savings but which will not result in missed opportunities to collect valid data in support of the fundamental research objectives. For example, collection of data and/or specimens that can be stored without loss of integrity and then analyzed at a later date using other funding sources may address this consideration.

vi) Contractor Contribution

The focus and operational requirements of this contract proposal is on physiological and subclinical medical morbidity. Because of the highly sensitive nature of police work and the vulnerabilities of police officers, this contract will not identify any measure of psychological function or social organization as an objective of the contract. However, the contractor is expected to bring to the study demonstrated and established leadership as well as operational expertise in the psychosocial arena in order to provide for a highly integrated effort among the major scientific disciplines involved in stress research. Accordingly, the technical evaluation criteria will include an assessment of demonstrated and documented history as well as expertise in psychosocial evaluation of police communities coupled with capacity to collect and operationally manage data derived from physiological and subclinical medical morbidity measurements. This assessment will include the offeror's intent and plan to add to the study psychosocial evaluations and/or measurements. Thus, the data derived by the addition of psychosocial measures and assessments specific to the study and the attendant examination are not a deliverable of the contract, nor is their collection and management directly reimbursable by the contract. The contractor will retain ownership of such data, and their use in analyses integrating the physiological and subclinical morbidity measurements will be at the sole discretion of the contractor.

2) Requirements and Tasks

a) General

Throughout the period of performance the contractor shall provide appropriate senior personnel with expertise in chronic disease epidemiology as well as in clinical neuroendocrine, cardiovascular, and Type 2 diabetic disease; measurement and assessment of psychological characteristics and of social environments in law enforcement communities; noninvasive imaging measurement and analysis; the collection, management, storage, and laboratory analysis of tissue and human fluid specimens; the collection, recording, transcription, electronic coding, editing, and QC analysis of data; and the management of human observational and clinical surveys and longitudinal studies. These personnel will:

- i)** Take responsibility in particular scientific areas for protocol development, including leadership and participation in subcommittees;
- ii)** Recruit and examine a population-based sample of police officers with sex, racial/ethnic, and age characteristics described in section 2 b) ii) (1) below;

- iii)** Participate in committees, such as the Steering Committee, the Operations and Data Management Committee, the Publication and Data Analysis Committee, and other subcommittees as appropriately identified by the Steering Committee;
- iv)** Be directly involved and responsible for data collection and quality assurance (QA) activities;
- v)** Work cooperatively with other Contractor investigators, potential subcontractors such as an imaging reading center and/or a biomedical laboratory, archiving and specimen repository centers, and the NIOSH Project Office staff and investigators in all relevant aspects of study execution; and
- vi)** Actively participate in data analysis and publication.

b) Specific

- i)** During the first 6 months of the contract the Contractor shall:
 - (1) Participate in study protocol development and pilot testing. The protocol for the examination will be completed prior to pilot testing, and if required priority will be given to obtaining clearance from the Office of Management and Budget (OMB). After draft protocols have been developed and approved by the Steering Committee, staff are to be trained for the examination. Pilot testing will consist of performing the examination, according to the draft Manual of Operations, in approximately 9 volunteers who are not study participants. The pilot tests also are to include shipping specimens to the appropriate laboratories and transmission of images to the appropriate reading centers. Final modifications to the Manuals of Operations are to be made based on the pilot test results at the direction of the Operations and Data Management Committee.
 - (a) Provide representation for Steering Committee and subcommittee meetings as appropriate. Steering Committee representatives may also be identified as subcommittee representatives. Steering Committee meetings will take place 1) every 3 months for year 1 at the contractor site, 2) every 6 months thereafter alternating between the NIOSH Project Office and the site, 3) an additional meeting 3 months prior to the end of the contract at the contractor site, and 4) the final meeting at the NIOSH Project Office (see Figure 1). Subcommittee meetings will generally take place in conjunction with Steering Committee meetings when scheduled at the contractor site, and by conference call as needed by the demands of the study.
 - (b) Actively participate in development of the study protocol, including the assumption of lead roles for development of particular aspects of the protocol.
 - (c) Actively plan and conduct pilot testing for examination components as specified in the protocol. Plan pilot testing to include all components of the exam, including Reading Center activities (see section 2) b) iii) below), specimen collection and management protocols, data management and QC activities, and overall QA activities. The pilot test should be conducted on no more than 9 volunteers. Repeat measurements should be planned for any examination component for which reproducibility is in question.
 - (d) Redesign and implement changes in protocol as recommended by the Steering Committee based on pilot test results.
- ii)** During the 3-year period, beginning 6 months after the start and ending 6 months before completion of the contract, the Contractor shall:

- (1) Using methods approved by the Steering Committee, identify a demographically defined population-based study sample from which a representative sample of active police officers will be recruited with specified sex, ethnic, and age characteristics using methods appropriate to 1) assure representation of these characteristics in the cohort population, 2) assure maximal participation, and 3) position the study to be able to address future scientific questions involving longitudinal and follow-up designs outside and beyond this contract proposal. Specific recruitment requirements include:
- (a) Design, implement and maintain methods for participant recruitment and tracking. The means by which a sampling frame is identified and its linkage to the study sample should be explicitly described. These systems should include procedures for maximizing participant response rates and for maintaining current contact information for potential subsequent follow-up studies. The recruitment system will include systems for recruiter management, tracking of contacts with potential eligible participants, and reporting contact status and response rates based on standard definitions applicable to this study design.
 - (b) Design and implement participant enrollment schedules that provide for approximate random ordering of enrollment with respect to demographic characteristics. This is done in order to avoid systematic trends in measured characteristics and will facilitate the assessment and control of measurement temporal drift in clinical laboratory measurements. This element should be integrated with recruitment systems appropriately to avoid interference with optimization of response rates.
- (2) Using forms and procedures approved by the Steering Committee, obtain informed consents taking into consideration potential ethical requirements for separate consents for use of different types of data to be derived from the examination (e.g., demographic, biochemistry, genetic, etc.).
- (3) Using equipment and personnel resources to be provided by the contractor, perform clinic examinations using protocols approved by the Steering Committee which include the following (see section **1) b) v)** above for a complete list of examination components):
- (a) Personal identification information (Name, contact information, follow-up information). Consideration of Human Subjects Review Board requirements to protect the privacy of participants needs to be taken in consideration in balancing the objective of positioning the research effort to address future scientific questions involving longitudinal and follow-up designs that may be funded by mechanisms outside and beyond this contract proposal. Data to be provided as a deliverable should have personal identifiers removed, but the contractor should retain the capacity to meet the positioning objective for future research.
 - (b) Information on fundamental demographic characteristics to meet recruitment requirements (see section **2) b) ii)** (1) above), medical history, smoking history, anthropometry, casual blood pressure, resting pulse, EKG.
 - (c) Clinical assessment of orthostatic hypotension.
 - (d) Heart rate variability using electronic ambulatory monitoring during standard provocation scenarios with data in the form of a continuous ECG time series.
 - (e) 1) Phlebotomy, buccal smears, and/or other tissue/fluid sampling to obtain the appropriate specimen for the laboratory evaluation of HDL and LDL cholesterol, fasting triglyceride, glucose intolerance, fasting insulin level, C-reactive protein, fibrinogen, and DNA; 2) processing of the appropriate specimen, and 3) long-term storage of said specimens. As appropriate to the laboratory evaluation, blood specimens should be processed to allow for low temperature (-70°C) long-term storage either at site or for transport to other laboratories.

Plan that approximately 20 mL of blood will be drawn into three tubes and divided into 16 microvials for shipping to laboratories and long-term storage. Provide for refrigerated centrifugation, temporary storage at low temperature, and shipping with dry ice for blood specimens.

- (f) Consistent with a protocol approved by the Steering Committee, obtain, process, and store multiple saliva specimens on individual participants at timings concordant with established provocation protocols for measuring cortisol HPA axis function. Saliva is the preferred specimen source as it is easily obtained with little to no discomfort to the participant. However, the proposal may suggest utilization of another specimen source provided sufficient justification is provided. Information regarding the amount of the measured cortisol that is free and biologically active if blood is chosen as the body fluid for assessment must be provided. These specimens will be provided to NIOSH investigator staff for laboratory analysis, and the Contractor should address the following requirements:

(i) Collection of Samples:

1. Provide information regarding the daily secretion pattern of the end-product of this negative feedback axis (i.e., cortisol). This includes information about the response of the axis to a natural endogenous challenge (e.g., awakening) as well as an imposed challenge (e.g., metabolic or nutritional challenge, psychological challenge, etc.). This information includes a sufficient number of samples to determine change from baseline as well as the shape of the response curve following the challenge. During a given challenge the contractor must ensure as much as possible uniformity of the challenge situation. For example, if a midday meal is chosen as a metabolic challenge the contractor should ensure 1) all subjects consume the same breakfast or snack prior to the challenge meal, 2) the quantity of challenge is standardized, and 3) the timing of specimen collection following challenge is standardized.
2. Insure by instruction and demonstration that each participant provides an adequate amount of saliva at each collection point within the protocol to allow for analysis of duplicates in the cortisol assay and to allow sufficient material to be frozen for future analysis of “as-yet-to-be identified” markers of stress. Specimens should be labeled and coded to insure proper identification of those obtained on the same individual.
3. Ensure each participant understands the importance of collecting the saliva samples in a timed fashion and of keeping a written record of their stress level at the time the sample is collected.
4. Specimens should be collected utilizing a device (e.g., Salivette manufactured by Sarstedt or a similar device either manufactured or home-made) that will guarantee saliva is not contaminated with substances (e.g., citric acid, food particles, etc.) that can interfere with the assay of the sample for cortisol or with the future assay of the saliva for other steroids or agents related to stress (e.g., alpha amylase).
5. Determine whether participants are taking medications (e.g., prednisone, dexamethasone, etc.) that would interfere with evaluation of cortisol.

(ii) Storage of Samples

1. Provide adequate storage of the saliva specimens until they are transported to NIOSH for laboratory analysis. Saliva can be stored at room temperature but the participant should be informed that refrigeration of the sample prior to their return to the contractor is preferred. The contractor should obtain information from each participant about the storage of the saliva prior to return to the contractor. The

contractor should ensure the samples are not overheated (e.g., left in car in summer, etc.).

2. Ensure appropriately labeled saliva specimens are sent to NIOSH in an expeditious fashion following their return to the contractor by the participant.

Assessment of the Sympathetic Nervous System: In responding to challenges or stressors the body relies on activation of not only the HPA axis but also the sympathetic nervous system. Activation of these systems results in the metabolic and physiological changes that allow the body to cope with stress; however, the continued activation of either system for protracted periods is believed to have adverse effects. To adequately address the health consequences of chronic stress it is desirable to be able to assess the status of sympathetic nervous system as well as the HPA axis in a population believed to be highly stressed. The contractor is encouraged to propose potential methods by which the function and health of the sympathetic nervous system may be assessed in the context of this study design. It is anticipated that these methods will involve measurements of substances released due to activation of the sympathetic nervous system in response to challenge (physiological, functional, etc.). It is most desirable to utilize biochemical markers that can be measured in easily accessible specimen sources such as saliva; however, other measurements (e.g., heart rate variability from a standardized provocation) may be suggested with attendant consideration of conceptual relevance, logistical limitations, and demand on participants.

- (g) Dual energy X-ray absorptiometry (DEXA) measurements characterizing fat, lean tissue, and bone mass and density as well as respective tissue proportions for the whole body as well as the following specified regions:
- (i) Left and right arm
 - (ii) Left and right leg
 - (iii) Lumbar spine
 - (iv) Thoracic spine
 - (v) Pelvis
 - (vi) Trochanter, intertrochanter, neck, ward's triangle, total right and left hip
 - (vii) Left and right wrist

The Contractor is expected to provide DEXA equipment capable of obtaining the aforementioned measurements. The Contractor must document performance and safety specifications. Such equipment must be capable of both regional and whole body measurements, including body composition analysis. Bone mineral density measurement precision should be less than 1%. Total radiation exposure for the entire exam should meet acceptable and documented standards. Reanalysis of data at later dates, automatic bone mapping for differentiation of soft tissue from bone, capacity to store patient records and data on external media, among other capabilities, are desirable performance features contributing to efficiencies.

- (h) With respect to DEXA measurements, the following activities will be established by the contractor:
- (i) Develop and establish, at the direction of the Steering Committee a final protocol for DEXA examinations during the clinical examination.
 - (ii) Demonstrate accuracy and reliability on an ongoing basis.
 - (iii) As part of an overall quality assurance program, train and oversee quality control monitoring of measurements by DEXA technicians in the details of the examination.

Training and certification should be documented and provided to the Steering Committee. Specifically, this documentation should address:

1. Training and certification of technicians during the protocol development/pilot testing phase, including retraining and recertification of technicians as needed during the examination period. Specific detailed plans for this training, including proposed curriculum and number of studies to be performed by technicians in training must be included in the proposal.
 2. Train and certify new technicians when turnover occurs.
- (iv) Develop, oversee, and evaluate a pilot study DEXA protocol.
- (v) Perform measurements in 9 volunteers according to the developed protocol as part of the protocol development/pilot testing phase.
- (vi) Provide documentation of a system of assessment for data quality for each examination of each subject throughout the study that will include characterization of measurement error and limits of acceptability. These duties will involve: 1) analysis of pilot data and of continuing quality control data, 2) report of results to the Steering Committee, and 3) design and implementation of necessary corrective actions.
- (vii) Perform approximately 800 to 1,000 examinations, including quality assurance activities, and provide data results to a central data management activity.
- (viii) Provide evidence of a quality assurance program to include 1) written standard operating procedures (SOPs), 2) quality control activities, and 3) monitoring of performance to ensure uniformity of data collection throughout the examination period. Report monitoring results to the Steering Committee.
- (i) Ultrasonography of the internal and common carotid arteries, using standard research-based ultrasonography techniques under direction of an ultrasound Reading Center and a local physician-ultrasonographer, to include the following measurements:
- (i) Vessel interfaces: Near and far wall adventitia-periadventitia, media-adventitia, lumen-intima of both common carotid arteries, carotid bulbs, and internal carotid arteries.
 - (ii) Wall thicknesses: Mean and maximum intimal-medial thickness of near and far walls of right and left common carotid arteries, carotid bulbs, and internal carotid arteries.
 - (iii) Minimum residual lumen of the common and internal carotid arteries.
 - (iv) Vessel width: Mean and maximum width of the common carotid arteries, carotid bulbs, and internal carotid arteries.
 - (v) In the assessment of stenosis, Doppler frequency shift or velocity at point of maximum disease.
 - (vi) Lesion characteristics, such as homogeneity, density, and regularity of surface. In the right and left internal carotid arteries, images will include two to three longitudinal views centered on the largest lesion, or at bifurcation if there is no lesion, as well as a single lateral view of the distal 10 mm of each common carotid artery.

- (j) Measures of flow mediated endothelial function as well as vascular stiffness, using ultrasound imaging of the forearm or other noninvasive technique. The Contractor, working in collaboration with research-based expertise either within their institution, a subcontractor, and/or Reading Center, will establish the protocol and specific quantitative measures of endothelial function and vascular stiffness. This will include pilot work. The Contractor is to provide necessary ultrasonography equipment, documenting performance specifications that will capture the aforementioned measurements (see **2 b) ii) (3) (h)** and (i) above).

iii) During the period from 3 months after the start until the end of the contract, the Contractor shall:

- (1) Beginning in the pilot period and extending to 3 months prior to the end of the contract, establish, develop, and maintain Reading Center activities for all ultrasound image collections, including carotid arteries (see **2 b) ii) (3) (g)** above) and brachial forearm assessment of endothelial function and vascular stiffness (see **2 b) ii) (3) (h)** above). Reading Center activities may be established, developed, and maintained by subcontract. If so, the subsequently described requirements and tasks represent performance activities of the subcontractor.

Such activities will include:

- (a) Develop and establish, at the direction of the Steering Committee a final protocol for ultrasound examinations during examination. The protocol will specify the techniques to measure wall thickness and lesion characteristics as well as potential physiological characteristics in the carotid arteries in an examination not to exceed 30 minutes of participants' time (examination time). The proposal should detail the proposed reading method. It should describe any offline analysis systems to be used, and should provide data on validity and reproducibility of proposed reading methods.
- (b) Measure characteristics listed in section **2 b) ii) (3) (g)** above.
- (c) In collaboration with the Steering Committee, establish appropriate measures and then measure these characteristics of brachial forearm endothelial function and vascular stiffness (see **2 b) ii) (3) (h)** above).
- (d) Demonstrate accuracy and reliability on an ongoing basis.
- (e) In collaboration with Contractor examination staff as part of an overall quality assurance program, train and oversee quality control monitoring of measurements by ultrasound technicians in the details of the ultrasound examination. Training and certification should be documented and provided to the Steering Committee. Specifically, this documentation should address:
- (i) Training and certification of technicians during the protocol development/pilot testing phase, including retraining and recertification of technicians as needed during the examination period. Specific detailed plans for this training, including proposed curriculum and number of studies to be performed by technicians in training must be included in the proposal.
- (ii) Train and certify new technicians when turnover occurs.

If the Reading Center is acting as a subcontractor remote from the examination site, documentation and certification should be in collaboration with an on-site physician-ultrasonographer who will supervise performance of ultrasound studies and contribute to protocol development, quality assurance, and data analysis.

- (f) In collaboration with Contractor examination staff as part of an overall quality assurance program, train and oversee quality control monitoring and certify the ultrasound readers in interpretation of studies and reading conventions developed in the final ultrasound protocol. Training and certification should be documented and provided to the Steering Committee. Specifically, this documentation should address:
 - (i) Training and certification of readers during the protocol development/pilot testing phase, including retraining and recertification of technicians as needed during the examination period. Specific detailed plans for this training, including proposed curriculum and number of studies to be performed by technicians in training must be included in the proposal.
 - (ii) Train and certify new readers when turnover occurs.
 - (g) In collaboration with Contractor examination staff, develop, oversee, and evaluate a pilot study protocol.
 - (h) Perform measurements in 9 volunteers at the Contractor examination facility Center, according to the developed protocol and transmit all data to the Contractor as part of the protocol development/pilot testing phase.
 - (i) Provide documentation of a system of assessment for data/image quality for each examination of each subject throughout the study that will include characterization of inter- and intra-individual variation among technicians and readers and limits of acceptability will be defined. The Reading Center will 1) collaborate with Contractor examination staff in the analysis of pilot data and of continuing quality control data, 2) report results to the Steering Committee, and 3) design and implement necessary corrective actions.
 - (j) Perform readings, information abstractions, and interpretations for no more than 1,000 examinations, including quality assurance activities.
 - (k) If the Reading Center is remote from the examination site, transmit all measurement data for a given participant to the Contractor in an agreed-upon format within thirty days of receipt of measurements.
 - (l) In collaboration with Contractor staff, provide evidence of a quality assurance program to include 1) written standard operating procedures (SOPs), 2) quality control activities, and 3) monitoring of performance to ensure uniformity of data collection throughout the examination period. Report results of monitoring to the Steering Committee.
- (2) Design, implement and maintain central data base and specimen management systems. Documented capacity to address issues of security, storage, and preservation of study data and specimens is required. Specific requirements include:
- (a) Coordinate the collection, transmittal, and integration of all examination, laboratory, and reading center data, as well as quality control data into the main data base during the pilot/testing phase of study and during the full scale examination.
 - (b) Implement and maintain a system to archive records and specimens including appropriate backup systems to prevent loss or damage. This system should provide for cataloging information about specimens, including type, amount, previous thawing and specific location in the repository. The specimen storage system should also include alarm systems, including persons responsible for responding to alarms and managing freezers in the event of power failure. Other issues to be addressed by potential contractors include safeguards based on

storage of multiple aliquots from individual participants in case of freezer failure, and the responsibility and certification of personnel responsible for managing freezers.

- (c) Provide regular quarterly reports for the Steering Committee describing the number and type of specimens as well as location and status.
 - (d) One year before the end of the contract or earlier provide a draft proposal outlining the final analysis data set structure including file names and variable naming conventions for all examination components.
 - (e) Approximately six months before the end of the contract provide a draft of data description manuals including descriptions, names, and units of measurement for all variables along with supporting documents as appendices such as clinic data forms and laboratory result forms.
 - (f) Six months before the end of the contract provide an interim analysis data set as an example of the data structure for the final analysis data set which will be provided at the time of contract closure. This data set will be consistent with the documentation above and should consist of SAS files or SPSS files with variable labels that include a brief description of the variable along with its units of measurement.
 - (g) Within six months after the end of the examination perform all necessary data cleaning and merging to create a closed data analysis set for delivery to the NIOSH Project Office. This should include removal of all individual identifying information that may be in the hands of the Contractor for purposes of subsequent contact of participants. Data should be provided on CD ROMs.
 - (h) By the end of the contract provide final data documentation as detailed above in both hard copy format and electronic pdf format on a CD ROM.
- (3) Under the aegis of the Operations and Data Management Subcommittee, establish, develop, and maintain a data quality assurance activity.

Specific requirements for data quality assurance activities include:

- (a) Hold regular quarterly meetings, keep and circulate to appropriate committees and operational units meeting minutes documenting ongoing data quality issues.
- (b) Develop and maintain a quality assurance program for all clinic forms, laboratory, and instrument-based measurements. As part of an integrated quality assurance program, establish quality control methodologies and standards. Where warranted, provide for approximately 5% blind duplicate measurements (e.g., certain biochemical laboratory-based and imaging measures). Develop and modify as necessary similar standards for Reading Center measures. Include plans for assessment and control of measurement temporal drift during the examination for each laboratory and reading center measurement. Include assessment of stability of stored laboratory specimens.
- (c) Provide professional expertise and oversight of quality assurance activities in all measurement areas of performance as input to the Operations and Data Management Committee. This includes but is not limited to clinical chemistry assessment of all laboratory-based biochemical and physical measurements, and physical sciences quality assurance assessment of all imaging measurements.

- (d) Develop, maintain and modify as needed the Manual of Operations including written standard operating procedures for the implementation of all aspects of the study protocol. This includes but is not necessarily limited to sections on examination components including clinic flow, clinic forms, collection of laboratory specimens, handling and storage of specimens, transfer of specimens for laboratory analysis, laboratory analysis and reporting, and transfer of imaging data to and from reading centers.
 - (e) Provide reports to the Steering Committee and to the NIOSH constituted external Monitoring Board, which will include a review of collected data every three months for six months, then every six months thereafter. Verify completeness, timeliness, reliability, and accuracy of data collection and coding. Include in the review comparisons of measures of distribution of values between technicians/instruments as appropriate to the measurement method. Include development and modification of standards to identify outlying values, and initiate and coordinate separate review of these observations for accuracy with the appropriate Reading Center and biochemistry laboratories.
 - (f) Maintain logs of data received, edit checks conducted, and identified errors; pursue missing data and correctable errors by communication with the Reading Center and biochemistry laboratories within two weeks of receipt and review of data; and develop, maintain, and modify an audit trail for all data entry and data correction activities, including electronically transferred data.
 - (g) Establish quality assurance activities for keypunching and data transmittal.
 - (h) Establish and maintain certification and training of all staff involved in examination activities.
 - (i) Monitor scheduled maintenance of all examination equipment.
- (4) As directed by the Steering Committee, provide and/or participate in statistical analysis support for the following activities:
- (a) Provide statistical and data analysis support for all quality assurance activities.
 - (b) Participate in collaborations involving statistical analysis of data for presentation and publication of study results. The NIOSH Project Office will have professional statisticians available for the benefit of the contract. Beyond the site demands of data management, quality assurance, and quality control, potential contractors may avail themselves in collaborations with these personnel. The proposal should characterize the nature of such collaborations, drawing distinctions between data and statistical management at the site for which the contractor will be responsible, and collaborative activities involving NIOSH Project Office professional statisticians.
- (5) As directed by the Steering Committee, provide the following activities in the collection, management, and provision of tissue specimens: By tissue specimens are meant any human biological source such as but not necessarily limited to 1) any blood component such as whole blood, white cell buffy coat, plasma, or serum, 2) DNA which may be derived from cellular constituents of blood, 3) buccal smears capturing epithelium which may become the source of DNA, and/or 4) saliva.
- (a) As determined by the study design, the collection of single and multiple (i.e., multiple specimens on the same person) specimens from cohort participants.

- (b) Processing of specimens as appropriate to the source and intended use of the specimen. That is, specimens may need to be processed and stored with certain preservation methods in order to allow for appropriate biochemical preparation and analysis.
- (c) Storage of specimens appropriate to the source and to the long term utilization of the specimen. This may include freezing.
- (d) Transport of specimens under appropriate preservation conditions to biochemistry laboratories remote from the examination site.

As appropriate to the laboratory evaluation, blood specimens should be processed to allow for low temperature (-70°C) long-term storage either at site or for transport to other laboratories. Plan that approximately 20 mL of blood will be drawn into three tubes and divided into 16 microvials for shipping to laboratories and long-term storage. Provide for refrigerated centrifugation, temporary storage at low temperature, and shipping with dry ice for blood specimens.

iv) For the contract period the Contractor shall:

- (1) Hold periodic on-site contract meetings involving the Steering Committee, appropriate subcommittees, and the NIOSH Project Office. The NIOSH Contract Office may be involved in periodic meetings as determined by the Contract Office, and in those cases representatives of the Contractor's business office should be 1) responsive to agenda items of interest to the NIOSH Contract Office and 2) available to participate in these meetings. For planning purposes, these meetings will be held according to the following approximate schedule and location:
 - (a) At the beginning of the contract and month 3, 6, 9 and 12: on-site
 - (b) At month 18: NIOSH Project Office, Morgantown, West Virginia
 - (c) At month 24: on-site
 - (d) At month 30: NIOSH Project Office, Morgantown, West Virginia
 - (e) At month 36: on-site
 - (f) At month 42: NIOSH Project Office, Morgantown, West Virginia
 - (g) At month 45: on site
 - (h) At month 48 (end of contract): NIOSH Project Office, Morgantown, West Virginia
- (2) Plan for annual review of contract performance by an outside Monitoring Board convened by the NIOSH Project Office. Expenses for Monitoring Board travel will be borne by the NIOSH Project Office. The Contractor should plan for the Principle Investigator and two other investigators to travel to the NIOSH Project Office in Morgantown, West Virginia when contractor meetings are so scheduled.

v) For the period of month 12 through the end of the contract, under the direction of the Steering Committee, the Contractor shall:

- (1) During the 12th month of the study, produce a manuscript describing the design and purpose of the study.

- (2) Beginning in month 36 and extending to the end of the contract, identify a minimum of two topics on which two manuscripts will be written by contract and NIOSH investigators and submitted for publication in the peer reviewed literature. These topics should reflect a fundamental description of measurements and attendant associations underlying the design of the study.
 - (3) Beginning in month 36 and extending to the end of the contract, plan and begin to execute data analyses leading to the aforementioned manuscripts.
- vi)** During the last 6 months of the contract, the Contractor shall work collaboratively with appropriate NIOSH staff in the close out of the contract. Close out activities shall address but not necessarily be limited to:
- (1) Provision of deliverables.
 - (2) Review of contract performance at contractor meetings.
 - (3) Identification and completion plans for subsequent manuscripts in peer-reviewed journals.
 - (4) Development of post-contract activities consistent with the intent of positioning the research effort to address future scientific questions involving longitudinal and follow-up designs to be funded by mechanisms outside and beyond this contract.

c) Subordinate Tasks

Participate in other activities related to the successful completion of the project, as specified by the Steering Committee and/or NIOSH Project Office. This includes, but is not necessarily limited to the following:

- i)** Provide results of each examination and an indication of any abnormalities of clinical significance to the participant, and, with consent, to his/her physician. Provide recommendations for follow-up of abnormalities as appropriate.
- ii)** Enter and edit the results from study examinations and quality assurance activities, including blind duplicates, into a computer, using software appropriate to these activities, and transmit the data to the NIOSH Project Office on a regular basis (at least monthly) as specified in the study protocol. This includes transmission of quality control data to the NIOSH Project Office according to specifications of the study protocol.
- iii)** Identify and create abstracts and manuscripts for presentation at professional meetings and peer reviewed publication, respectively, with attendant approvals as identified in the schedule of deliverables by the NIOSH Project Office.
- iv)** Provide up-to-date lists of publications and presentations which result from the examination data collected under this contract. These lists are for a data base to be managed by the NIOSH Project Office.

3) Reports and Deliverables

a) Reports

- i)** Quarterly progress reports , indicating general progress in study activities and administrative issues; personnel with FTE level for the reporting period; changes in personnel; specific problems

encountered or anticipated and attempts to resolve such problems; and quality assurance and quality control activities as well as progress in publication activities.

- ii)** Monthly financial reports as described in Section F .
- iii)** A final report, due on or before expiration of the contract (2 copies), documenting and summarizing the results of the entire contract work, including recommendations and conclusions.
- iv)** With the final report, a summary of salient results achieved during the performance of the contract (2 copies).
- v)** Other items listed in the Deliverables Schedule in Section F.

4) Special Requirements/Considerations (as applicable):

- a)** Clearance of all forms used during participant recruitment, interim contact, and clinic examinations and scans may require being cleared by the Office of Management and Budget (OMB) prior to use in the study.
- b)** Human Subject Certification by the Contractor's IRB and the NIOSH HSRB must be obtained prior to participant contact. The contractor will be responsible for preparing and submitting to these boards. Additionally, if required by the Contractor's IRB, a study certificate of confidentiality must be obtained to protect genetic information from disclosure.
- c)** Access to a facility conducting research-based measurements of 1) body composition via Dual energy X-ray absorptiometry (DEXA) and 2) carotid morphology and brachial reactivity via ultrasonography is required. The facility must be able to accommodate the participants for this study during the required time frame and in a manner feasible for the conduct of the study. The facility should be accessible to the participants during convenient hours.
- d)** The Contractor shall supply all materials and facilities for the conduct of this study. Recourses are available for any laboratory based analyses conducted at the NIOSH laboratory in Morgantown, West Virginia (see g) below).
- e)** Utilization of genetic material and data related to genetic assessments for further research and development shall be the sole responsibility of the contractor and not a deliverable to NIOSH. However, a plan for the use of such material should accompany the proposal.
- f)** Industry/Third Party contributions shall be processed in accordance with Federal regulations and NIOSH policy.
- g)** Established laboratory competencies exist to measure cortisol with sponsoring NIOSH intramural staff, and costs associated with such measurements should not be factored into the proposal. This includes collection tubes, transportation, and any non-prescription oral agent the Steering Committee may approve as a physiological provocation of the HPA axis and/or sympathetic nervous system.

Section D - Packaging And Marking

D.1 Instructions for Shipment of Cortisol Samples

Packaging and marking of samples being shipped must comply with applicable Federal regulations and carrier requirements for transportation of potentially biohazardous samples. Samples are to be sent at room temperature in appropriate packaging. Samples should be sent for next day delivery using an account number provided by NIOSH to the following address:

Diane B. Miller, Ph.D
NIOSH/HELD/TMBB
1095 Willowdale Road , Room L-4316
Attention: Mary Ann Hammer
Morgantown, W V 26505

Section E - Inspection And Acceptance

FAR SOURCE	TITLE AND DATE
52.246-1	Contractor Inspection Requirements (Apr 1984)
52.246-5	Inspection of Services -- Cost-Reimbursement (Apr 1984)

E.1 Inspection and Acceptance (Jul 1999)

Inspection and acceptance of the articles, services, and documentation called for herein shall be accomplished by the Contracting Officer, or his duly authorized representative (who for the purposes of this contract shall be the Project Officer) at the destination of the articles, services or documentation.

(End of Clause)

Section F - Deliveries Or Performance

FAR SOURCE	TITLE AND DATE
52.242-15	Stop-Work Order (Aug 1989) (Alternate I) (Apr 1984)

F.1 Deliverable(s) Schedule

<u>Item</u>	<u>Description</u>	<u>Quantity</u>	<u>Delivery Schedule</u>	<u>Recipient</u>
1	Data from pilot study	1	May 1, 2004	Project Office
2	Consent forms (blank)	1	May 1, 2004	Project Office
3	Multiple specimens for NIOSH laboratory analysis from pilot study	9 people	May 1, 2004	Project Office
4	Examination data (by CD ROM) and specimens	800-1000 people	Monthly	Project Office
5	Quarterly Progress Reports	3 copies	Jan 1, 2004 to Aug 1, 2007	Project Office (2 copies) Contract Office (1 copy)
6	Abstract	1 copy	2 weeks prior to submission	Project Office
7	Manuscript*	1 copy	4 weeks prior to submission	Project Office
8	Manuscripts*	3	May 1, 2005 (1) Sept 30, 2007 (2)	Project Office
9	Financial Reports	1	Monthly	Contract Office
10	Draft Final Report	1	July 1, 2007	Project Office (1 copy)
11	Final Report	2	Sept 30, 2007	Project Office (1 copy) Contract Office (1 copy)

* Minimum number of distinct manuscripts from Contractor, in collaboration with NIOSH investigators, submitted for publication. See Section 2.C. *iii* and 2. b. v. (1), (2), and (3) of the Statement of Work for more specific information.

Report Content

1. Quarterly Progress Reports- The Contractor shall prepare and submit quarterly technical progress reports in narrative form which shall contain technical results of work accomplished during the reporting period. This report shall be in sufficient detail to disclose all work started and results achieved during the period, highlight any current problems which may impede performance, propose corrective action, and forecast work for the next quarterly period.
2. Draft Final Report - Prior to July 1, 2007, the Contractor shall prepare and submit to the Government a draft final report covering in detail all the work accomplished under the contract. The final report shall be prepared in accordance with the specifications in Section C and shall document and summarize the entire contract work. It should also include recommendations and conclusions based on the experience and results obtained. It must include an analysis of salient findings, a presentation of general conclusions, and any guidance or recommendations deemed pertinent for future consideration by NIOSH. The Government shall be allowed 6 weeks to review the draft and notify the contractor in writing of approval or recommend changes to be made in the final copy. If the Government does not approve or recommend changes within the 6 weeks of receipt of the draft of the final report, it shall be deemed approved.
3. Final Report—Prior to September 30, 2007, the Contractor shall furnish the Government with a hard copy of the final report and one electronic version in MS Word, using MS Excel for spreadsheets and PowerPoint for graphics.
4. Monthly Financial Report-- Within ten (10) days after the end of each month, the Contractor shall prepare and submit a monthly financial report which will summarize in tabular form the expenditures for the current month and the cumulative expenditures through the current month. The report shall contain a detailed actual cost breakdown in the same categories which appeared in the contractor's cost proposal (including the extent of cost sharing) both for the current month and cumulatively through the current month. Any gross deviations from proposed expenditures should be explained. In addition, any outstanding commitments as of the end of the reporting period shall also be reflected in the report.

F.2 Period of Performance (Jul 1999)

The effective date of this contract shall be the date shown on Page 1 of this contract. The contractor shall complete the effort and submit all items specified under Section C. within 49 months after the effective date of the contract. All documents must be submitted as a hard copy and in electronic format in MS Word, using MS Excel for spreadsheets and PowerPoint for graphics.

F.3 Delivery of Reports

One copy of each report shall be delivered prepaid to:

Centers for Disease Control and Prevention (CDC)
Acquisition and Assistance Field Branch- Pittsburgh
P.O. Box 18070
626 Cochran's Mill Road, Bldg 140
Pittsburgh, PA 15236-0070

Attention: Florence P. Black
Contract No.: 200-2003-01580

All remaining copies of reports, as well as Item 4, shall be delivered prepaid to the Government Project Officer designated by the Contracting Officer at the address provided at award.

Section G - Contract Administration Data

G.1 Provisional Billing Rates

Subject to provisions of the clause of Section I entitled "Allowable Cost and Payment" FAR 51.216-7, the following negotiated rates shall be used as provisional rates pending establishment of final negotiated rates;

Indirect Cost Element	Rate	Base	Period
Facilities and Administration	(b)(4)	Direct Costs	Award of contract until amended

G.2 Travel Costs

Reimbursement of travel costs under this contract shall be in accordance with OMB Circular A-21, Cost Principles for Educational Institutions, Section J.48.

G.3 Project Officer (Jul 1999)

Performance of the work hereunder shall be subject to the technical directions of the designated Project Officer for this contract.

As used herein, technical directions are directions to the Contractor which fill in details, suggests possible lines of inquiry, or otherwise completes the general scope of work set forth herein. These technical directions must be within the general scope of work, and may not alter the scope of work or cause changes of such a nature as to justify an adjustment in the stated contract price/cost, or any stated limitation thereof. In the event that the Contractor feels that full implementation of any of these directions may exceed the scope of the contract, he or she shall notify the originator of the technical direction and the Contracting Officer in a letter separate of any required report(s) within two (2) weeks of the date of receipt of the technical direction and no action shall be taken pursuant to the direction. If the Contractor fails to provide the required notification within the said two (2) week period that any technical direction exceeds the scope of the contract, then it shall be deemed for purposes of this contract that the technical direction was within the scope. No technical direction, nor its fulfillment, shall alter or abrogate the rights and obligations fixed in this contract.

The Government Project Officer is not authorized to change any of the terms and conditions of this contract. Changes shall be made only by the Contracting Officer by properly written modification(s) to the contract.

The Government will provide the Contractor with a copy of the delegation memorandum for the Project Officer. Any changes in Project Officer delegation will be made by the Contracting Officer in writing with a copy being furnished to the Contractor.

(End of Clause)

G.4 Payment by Electronic Funds Transfer (Jan 2000)

(a) The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-34, Payment by Electronic Funds Transfer—Other than Central Contractor Registration, incorporated by reference in Section I, requires the contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

(b) The contractor shall make the designation by submitting the form titled "ACH Vendor/Miscellaneous Payment Enrollment Form" to the address indicated below. Note: The form is either attached to this contract (see Section J, List of Attachments) or may be obtained by contacting the Contracting Officer or the CDC Financial Management Office at (404) 687-6666.

(c) In cases where the contractor has previously provided such designation, i.e., pursuant to a prior contract/order, and been enrolled in the program, the form is not required.

(d) The completed form shall be mailed after award, but no later than 14 calendar days before an invoice is submitted, to the following address:

Centers for Disease Control and Prevention
Box 15580 MS D-06
Attn: Accounts Payable ACH Dept
Atlanta GA 30333

The completed form may also be faxed to 404-638-5342.

G.5 Voucher/Invoice Submission

All vouchers shall reflect the exact dates covered (i.e., 1-28 September 1999). The cost categories set forth in the vouchers shall correspond by nomenclature to the cost categories set forth in the cost proposal on which the final negotiated cost figures are based. All vouchers shall reflect itemized cumulative totals of costs incurred on the contract to the date of that voucher. The voucher shall also contain itemized totals for the billing period of that voucher. Vouchers shall be submitted in an original and three (3) copies to the Contracting Officer at the address shown in Block 7 of the cover sheet (SF 33).

The Contractor shall, in addition to the above requirements, submit a detailed breakout of costs as supporting backup and shall place the following signed Contractor Certification on each invoice/voucher submitted under this contract:

I certify that this voucher reflects (fill in Contractor's name) request for reimbursement of allowable and allocable costs incurred in specific performance of work authorized under Contract (fill in contract number), and that these costs are true and accurate to the best of my knowledge and belief.

(Original Signature of Authorized Official)
Typed Name and Title of Signatory

The date of receipt of a proper invoice/voucher by the Contracting Officer shall be used for the purpose of Prompt Payment Act time computations.

(End of Clause)

G.6 Reimbursement of Cost (Apr 2000)

(a) For the performance of this contract, the Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with the clause entitled Allowable Cost and Payment in Section I, Contract Clauses. Examples of allowable costs include, but are not limited to, the following:

(1) All direct materials and supplies which are used in the performing of the work provided for under the contract, including those purchased for subcontracts and purchase orders.

(2) All direct labor, including supervisory , that is properly chargeable directly to the contract, plus fringe benefits.

(3) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

(4) Special expenditures which, upon request from the Contractor, the Contracting Officer approves as being an allowable cost under this contract, such as purchase or lease of office furniture or equipment, etc..

(5) All travel costs plus per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract. These costs will be in accordance with the Contractor's policy and subject to the following:

(i) Air travel shall be by the most direct route using "air coach" or "air tourist" (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).

(ii) Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.

(iii) Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).

(iv) Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

(b) Except as stated herein, the Contractor shall not incur costs unless the prior written authorization of the Contracting Officer has been obtained. When costs are incurred without such prior authorization, with the intent of claiming reimbursement as direct costs, it shall be at the contractor's risk.

(End of Clause)

G.7 Subcontracting Program Reports (May 1998)

(a) The Contractor shall submit the reports listed below in accordance with the instructions and within the time periods specified on the report forms:

(1) Standard Form 294, Subcontracting Report for Individual Contracts.

(2) Standard Form 295, Summary Subcontract Report.

(b) In addition to the reporting information specified on the report forms, the Contractor shall provide, in the "Remarks" block on each Standard Form 294 submitted, a narrative of the progress made in fulfilling the small business and small disadvantaged business subcontracting goals contained in its approved plan.

(c) The Contractor shall report to the Contracting Officer any difficulties encountered in achieving the goals and shall describe the action being taken to overcome the difficulties.

(End of Clause)

G.8 Evaluation of Contractor Performance (Service) (Jan 2000)

(a) Purpose

In accordance with FAR 42.1502, the Contractor's performance will be periodically evaluated by the Government, in order to provide current information for source selection purposes. These evaluations will therefore be marked "Source Selection Information."

(b) Performance Evaluation Period

The Contractor's performance will be evaluated after completion of the contract.

(c) Evaluators

The performance evaluation will be completed jointly by the Project officer and the Contracting officer.

(d) Performance Evaluation Factors

The contractor's performance will be evaluated in accordance with the attachment listed in Section J titled Performance Evaluation Report.

(e) Contractor Review

A copy of the evaluation will be provided to the contractor as soon as practicable after completion of the evaluation. The contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 30 calendar days after receipt of the evaluation.

(f) Resolving Disagreements Between the Government and the Contractor

Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, contractor's response, and review comments, if any, will be retained as part of the evaluation.

(g) Release of Contractor Performance Evaluation Information

The completed evaluation will not be released to other than Government personnel and the contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the contractor being evaluated as well as impede the efficiency of Government operations.

(h) Source Selection Information

Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.

(i) Retention Period

The agency will retain past performance information for a maximum period of three years after completion of contract performance for the purpose of providing source selection information for future contract awards.

(End of Clause)

G.9 Contracting Officer (Jul 1999)

(a) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.

(b) No information, other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

(End of Clause)

G.10 Contract Communications/Correspondence (Jul 1999)

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number from Page 1 of the contract.

(End of Clause)

Section H - Special Contract Requirements

H.1 HHSAR 352.270-8b Protection of Human Subjects (Jan 2001)

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH). The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgement or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(c) If at any time during the performance of this contract, the Contracting officer determines, in consultation with the OPRR, NIH, that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OPRR, NIH, terminate this contract in a whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Health and Human Services Human Subject Assurances.

(End of clause)

H.2 Review and Comment (May 1998)

All materials developed or information of whatever nature resulting from work performed under this contract shall be submitted to the Project Officer for review and comment prior to publication or dissemination.

H.3 Contract Printing

This contract does not provide for printing in excess of the prescribed limits established by the Joint Committee on Printing. To the maximum extent practicable, printing will be performed by the Government as a cost savings measure.

H.4 Incorporation of Technical Proposal

The Contractor's technical proposal pages 32 through 67 dated May 23, 2003, submitted in response to RFP 2003-N-00764, is hereby incorporated into the contract by reference. The Contractor shall perform the work substantially set forth in the technical proposal. Any revisions to the technical proposal that would significantly alter the

technical approach must be approved in writing by the Contracting Officer. In the event a conflict between Section C, Statement of Work, and the Contractor's technical proposal, Section C. shall take precedence.

H.5 Identification of Data

The Contractor shall identify the technical data delivered to the Government as required by this contract with the number of the contact and the name and address of the Contractor or subcontractor who generated the data.

H.6 HHSAR 352.270-5 Key Personnel (Apr 1984)

The personnel specified in this contract are considered to be essential to the work being performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The contract may be modified from time to time during the course of the contract to either add or delete personnel, as appropriate.

(End of clause)

H.7 Key Personnel Listing

<u>Name</u>	<u>Project Title</u>
Dr. John Violanti	Principal Investigator

H.8 Prohibition on the Use of Appropriated Funds for Lobbying Activities (Jul 1999)

The contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 10, United States Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities, see FAR Subpart 3.8 and FAR Clause 52.203-12.

In addition, the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or

agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature.

H.9 Smoke Free Environment (Jul 1999)

In compliance with Department of Health and Human Services (DHHS) regulations, all contractor personnel performing work within CDC/ATSDR facilities shall observe the CDC/ATSDR smoke-free working environment policy at all times. This policy prohibits smoking in all CDC/ATSDR buildings and in front of buildings which are open to the public. This policy is also applicable to contractor personnel who do not work full-time within CDC/ATSDR facilities, but are attending meetings within CDC/ATSDR facilities.

(End of Clause)

H.10 Representations, Certifications and Other Statements of Offerors (Jul 1999)

The Representations, Certifications and Other Statements of Offerors submitted by the Research Foundation of SUNY dated May 23, 2003 are hereby incorporated by reference, with the same force and effect as if they were given in full text.

(End of Clause)

H. 11 Data Subject to Confidentiality Requirements (May 1998)

The type(s) of data subject to the clause at 352.224-70, Confidentiality of Information, which has been incorporated by reference in Section I, are as follows:

All data obtained from or about the study participants.

Following are the requirements for handling these data:

Data must be handled in accordance with the protocols developed for the study and approved by NIOSH.

H.12 Inclusion of Woman and Racial and Ethnic Minorities in Research (Jan 2000)

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black, and Hispanic. Offerors shall ensure that women, racial, and ethnic minority populations are appropriately represented in proposals for research projects involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the proposal. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the Federal Register notice dated September 15, 1995.

(End of Clause)

H.13 Government Property (Jan 2000)

(a) Government-Furnished Property (GFP). The Government reserves the right to supply the Contractor, as Government-furnished property, any additional supplies, equipment, and materials determined by the Contracting Officer to be necessary and in the best interest of the Government in the performance of this contract provided the property is furnished, or the Contractor is notified of the Government's intent to furnish it, prior to the Contractor's commitment to acquire such items.

(b) Contractor-Acquired Property (CAP). Regardless of the place of performance, when the costs of such items will be charged to the contract, the Contractor must receive written consent from the Contracting Officer prior to purchase of any item which requires such consent under FAR 52.244-2 (see Section I, FAR 52.244-2, paragraphs (c), (d) and (e)).

(c) If performance of this contract is within and on Government facilities, and the Government-furnished property or contractor-acquired property is for use only within or on the Government facilities, the control and accountable record keeping for such property shall be retained by the Government (see FAR 52.245-1, Property Records). The Contractor shall remain accountable for loss or damage, but will not be required to submit an annual inventory or place its own bar codes on the items. The Government will provide property labels and other identification for contractor-acquired Government property under this paragraph.

(d) If performance of this contract is not within Government facilities, and there is either Government-furnished property or contractor-acquired property being used in performance of the work, the Contractor shall be responsible for the control and accountable record keeping for such property in accordance with FAR Subpart 45.5 as supplemented by HHS Publication (OS) 74.115 entitled "Contractor's Guide for Control of Government Property," a copy of which will be provided upon request.

(e) The Chief of Material Management Branch, PGO, Centers for Disease Control and Prevention (CDC), is hereby designated as the Property Administrator for this contract. The Contractor agrees to furnish information regarding the Government property under this contract to the Property Administrator, an authorized representative, or a duly designated successor(s). The Contractor shall identify each item of equipment furnished by the Government to the Contractor or acquired by the Contractor using contract funds, with a suitable decal, tag, or other marking, as prescribed by the Property Administrator, and shall follow the guidance set forth in the "Contractor's Guide for Control of Government Property."

(End of Clause)

H.14 Year 2000 Compliance (Jul 1999)

Unless elsewhere exempted, information technology (if any) to be acquired under this contract/purchase order, which will be required to perform date/time processing involving dates subsequent to December 31, 1999, shall be Year 2000 compliant as defined in Federal Acquisition Regulation Part 39.002.

(End of Clause)

H.15 Notice of Restricted Award

Under governing regulations, Federal funds which are administered by the Centers for Disease Control and Prevention (CDC) shall not be expended by the awardee for research involving human subjects, nor shall human subjects be involved in research activities by the awardee under this award unless a satisfactory assurance of compliance with 45 CFR 46 is submitted to CDC by the awardee within 40 days of the date of issuance of this award and is subsequently approved by the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH). Each performance site (if any) must also assure compliance with 45 CFR 46 and receive OPRR's approval before expenditure of funds or involvement of human subjects. The present award is being made without OPRR-approved assurance of compliance with 45 CFR 46 with the following restriction: Only activities which do not directly involve human subjects (i.e., are clearly severable and independent from those activities that do involve human subjects); may be conducted by the awardee or individual performance sites pending OPRR approval of their respective assurance of compliance with 45 CFR 46.

Section I - Contract Clauses

Section I-1 - Clauses Incorporated By Reference

I.1 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

<http://www.arnet.gov/far>
<http://farsite.hill.af.mil/VFFARa.htm> or [VFFAR1.htm](http://farsite.hill.af.mil/VFFAR1.htm)

(End of Clause)

I.2 FAR 52.252-6 Authorized Deviations in Clauses (Apr 1984)

(a) The use in this solicitation or contract of any Federal Acquisition Regulation (48 CFR Chapter 1) clause with an authorized deviation is indicated by the addition of "*(Deviation)*" after the date of the clause.

(b) The use in this solicitation or contract of any HHSAR (48 CFR Chapter 3) clause with an authorized deviation is indicated by the addition of "*(Deviation)*" after the name of the regulation.

FAR SOURCE	TITLE AND DATE
52.202-1	Definitions (Dec 2001) (Deviations)(HHSAR 352.202-1)(Alt 1) (Jan 2000)
52.203-3	Gratuities (Apr 1984)
52.203-5	Covenant Against Contingent Fees (Apr 1984)
52.203-6	Restrictions on Subcontractor Sales to the Government (Jul 1995)
52.203-7	Anti-Kickback Procedures (Jul 1995)
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Jan 1997)
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (Jan 1997)
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (Jun 1997)
52.204-4	Printed or Copied Double-Sided on Recycled Paper (Aug 2000)
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Jul 1995)
52.215-2	Audit and Records -- Negotiation (Jun 1999)
52.215-8	Order of Precedence -- Uniform Contract Format (Oct 1997)
52.215-10	Price Reduction for Defective Cost or Pricing Data (Oct 1997)
52.215-11	Price Reduction for Defective Cost or Pricing Data -- Modifications (Oct 1997)
52.215-12	Subcontractor Cost or Pricing Data (Oct 1997)
52.215-13	Subcontractor Cost or Pricing Data -- Modifications (Oct 1997)

- 52.215-15 Pension Adjustments and Asset Reversions (Dec 1998)
- 52.215-17 Waiver of Facilities Capital Cost of Money (Oct 1997)
- 52.215-18 Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other Than Pensions (Oct 1997)
- 52.215-21 Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data -- Modifications (Oct 1997)
- 52.216-7 Allowable Cost and Payment (Dec 2002)
- 52.219-8 Utilization of Small Business Concerns (Oct 2000)
- 52.219-9 Small Business Subcontracting Plan (Jan 2002)
- 52.219-16 Liquidated Damages -- Subcontracting Plan (Jan 1999)
- 52.222-2 Payment for Overtime Premiums (Jul 1990)
- 52.222-3 Convict Labor (Aug 1996)
- 52.222-4 Contract Work Hours and Safety Standards Act -- Overtime Compensation (Sep 2000)
- 52.222-21 Prohibition of Segregated Facilities (Feb 1999)
- 52.222-22 Previous Contracts and Compliance Reports (Feb 1999)
- 52.222-26 Equal Opportunity (Apr 2002)
- 52.222-35 Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Dec 2001)
- 52.222-36 Affirmative Action for Workers with Disabilities (Jun 1998)
- 52.222-37 Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Dec 2001)
- 52.223-3 Hazardous Material Identification and Material Safety Data (Alternate I) (Jul 1995)
- 52.223-6 Drug-Free Workplace (May 2001)
- 52.223-14 Toxic Chemical Release Reporting (Oct 2000)
- 52.225-13 Restrictions on Certain Foreign Purchases (Jul 2000)
- 52.226-1 Utilization of Indian Organizations and Indian-Owned Economic Enterprises (Jun 2000)
- 52.227-1 Authorization and Consent (Jul 1995)
- 52.227-2 Notice and Assistance Regarding Patent and Copyright Infringement (Aug 1996)
- 52.227-3 Patent Indemnity (Apr 1984)
- 52.227-14 Rights in Data -- General (Alternate IV) (Jun 1987)
- 52.227-17 Rights in Data -- Special Works (Jun 1987)
- 52.230-2 Cost Accounting Standards (Apr 1998)
- 52.230-3 Disclosure and Consistency of Cost Accounting Practices (Apr 1998)
- 52.230-5 Cost Accounting Standards -- Educational Institution (Apr 1998)
- 52.230-6 Administration of Cost Accounting Standards (Nov 1999)
- 52.232-9 Limitation on Withholding of Payments (Apr 1984)
- 52.232-17 Interest (Jun 1996)

HHSAR SOURCE	TITLE AND DATE
352.216-72	Additional Cost Principles (Oct 1990)
352.224-70	Confidentiality of Information (Apr 1984)
352.228-7	Insurance -- Liability to Third Persons (Dec 1991)
352.232-9	Withholding of Contract Payments (Apr 1984)
352.233-70	Litigation and Claims (Apr 1984)
352.242-71	Final Decisions on Audit Findings (Apr 1984)
352.270-6	Publications and Publicity (Jul 1991)
352.270-7	Paperwork Reduction Act (Jan 2001)
52.232-18	Availability of Funds (Apr 1984)
52.232-22	Limitation of Funds (Apr 1984)
52.232-23	Assignment of Claims (Jan 1986)
52.232-25	Prompt Payment (Feb 2002)
52.232-34	Payment by Electronic Funds Transfer -- Other Than Central Contractor Registration (May 1999)
52.233-1	Disputes (Jul 2002)
52.233-3	Protest After Award (Aug 1996)
52.233-3	Protest After Award (Alternate I) (Jun 1985)
52.242-1	Notice of Intent to Disallow Costs (Apr 1984)
52.242-3	Penalties for Unallowable Costs (May 2001)
52.242-4	Certification of Final Indirect Costs (Jan 1997)
52.242-13	Bankruptcy (Jul 1995)
52.243-2	Changes -- Cost-Reimbursement (Alternate V) (Apr 1984)
52.244-5	Competition in Subcontracting (Dec 1996)
52.245-1	Property Records (Apr 1984)
52.245-5	Government Property (Cost-Reimbursement, Time-and-Material, or Labor-Hour Contracts) (Alternate I) (Jul 1985)
52.246-25	Limitation of Liability -- Services (Feb 1997)
52.247-63	Preference for U.S.-Flag Air Carriers (Jan 1997)
52.248-1	Value Engineering (Feb 2000)
52.249-6	Termination (Cost-Reimbursement) (Sep 1996)
52.249-14	Excusable Delays (Apr 1984)
52.253-1	Computer Generated Forms (Jan 1991)

Section I-2 - Clauses Incorporated In Full Text

I.2 FAR 52.215-19 Notification of Ownership Changes (Oct 1997)

(a) The Contractor shall make the following notifications in writing:

(1) When the Contractor becomes aware that a change in its ownership has occurred, or is certain to occur, that could result in changes in the valuation of its capitalized assets in the accounting records, the Contractor shall notify the Administrative Contracting Officer (ACO) within 30 days.

(2) The Contractor shall also notify the ACO within 30 days whenever changes to asset valuations or any other cost changes have occurred or are certain to occur as a result of a change in ownership.

(b) The Contractor shall --

(1) Maintain current, accurate, and complete inventory records of assets and their costs;

(2) Provide the ACO or designated representative ready access to the records upon request;

(3) Ensure that all individual and grouped assets, their capitalized values, accumulated depreciation or amortization, and remaining useful lives are identified accurately before and after each of the Contractor's ownership changes; and

(4) Retain and continue to maintain depreciation and amortization schedules based on the asset records maintained before each Contractor ownership change.

(c) The Contractor shall include the substance of this clause in all subcontracts under this contract that meet the applicability requirement of FAR 15.408(k).

(End of Clause)

I.4 FAR 52.244-2 Subcontracts (Aug 1998)

(a) *Definitions.* As used in this clause—

"Approved purchasing system" means a Contractor's purchasing system that has been reviewed and approved in accordance with Part 44 of the Federal Acquisition Regulation (FAR)

"Consent to subcontract" means the Contracting Officer's written consent for the Contractor to enter into a particular subcontract.

"Subcontract" means any contract, as defined in FAR Subpart 2.1, entered into by a subcontractor to furnish supplies or services for performance of the prime contract or a subcontract. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.

(b) This clause does not apply to subcontracts for special test equipment when the contract contains the clause at FAR 52.245-18, Special Test Equipment.

(c) When this clause is included in a fixed-price type contract, consent to subcontract is required only on unpriced contract actions (including unpriced modifications or unpriced delivery orders), and only if required in accordance with paragraph (d)(or (e) or this clause.

(d) If the contractor does not have an approved purchasing system, consent to subcontract is required for any subcontract that--

(1) Is of the cost-reimbursement, time-and-materials, or labor-hour type; or

(2) Is fixed-price and exceeds—

(i) For a contract awarded by the Department of Defense, the Coast Guard, or the national Aeronautics and Space Administration, the greater of the simplified acquisition threshold or 5 percent of the total estimated cost of the contract; or

(ii) For contracts awarded by a civilian agency other than the Coast Guard and the National Aeronautics and Space Administration, either the simplified acquisition threshold or 5 percent of the total estimated cost of the contract.

(e) If the Contractor has an approved purchasing system, the Contractor nevertheless shall obtain the Contracting Officer's written consent before placing the following subcontracts:

(f)(1) The Contractor shall notify the Contracting Officer reasonably in advance of placing any subcontract or modification thereof for which consent is required under paragraph (c), (d), or (e) of this clause, including the following information:

(i) A description of the supplies or services to be subcontracted.

(ii) Identification of the type of subcontract to be used.

(iii) Identification of the proposed subcontractor.

(iv) The proposed subcontract price.

(v) The subcontractor's current, complete, and accurate cost or pricing data and Certificate of Current Cost or Pricing Data, if required by other contract provisions.

(vi) The subcontractor's Disclosure Statement or Certificate relating to Cost Accounting Standards when such data are required by other provisions of this contract.

(vii) A negotiation memorandum reflecting --

(A) The principal elements of the subcontract price negotiations;

(B) The most significant considerations controlling establishment of initial or revised prices;

(C) The reason cost or pricing data were or were not required;

(D) The extent, if any, to which the Contractor did not rely on the subcontractor's cost or pricing data in determining the price objective and in negotiating the final price;

(E) The extent to which it was recognized in the negotiation that the subcontractor's cost or pricing data were not accurate, complete, or current; the action taken by the Contractor and the subcontractor; and the effect of any such defective data on the total price negotiated;

(F) The reasons for any significant difference between the Contractor's price objective and the price negotiated; and

(G) A complete explanation of the incentive fee or profit plan when incentives are used. The explanation shall identify each critical performance element, management decisions used to quantify each incentive element, reasons for the incentives, and a summary of all trade-off possibilities considered.

(2) The Contractor is not required to notify the Contracting Officer in advance of entering into any subcontract for which consent is not required under paragraph (c), (d), or (e) or this clause.

(g) Unless the consent or approval specifically provides otherwise, neither consent by the Contracting Officer to any subcontract nor approval of the Contractor's purchasing system shall constitute a determination --

(1) Of the acceptability of any subcontract terms or conditions;

(2) Of the allowability of any cost under this contract; or

(3) To relieve the Contractor of any responsibility for performing this contract.

(h) No subcontract or modification thereof placed under this contract shall provide for payment on a cost-plus-a-percentage-of-cost basis, and any fee payable under cost-reimbursement type subcontracts shall not exceed the fee limitations in FAR 15.404-4(c)(4)(i).

(i) The Contractor shall give the Contracting Officer immediate written notice of any action or suit filed and prompt notice of any claim made against the Contractor by any subcontractor or vendor that, in the opinion of the Contractor, may result in litigation related in any way to this contract, with respect to which the Contractor may be entitled to reimbursement from the Government.

(j) The Government reserves the right to review the Contractor's purchasing system as set forth in FAR Subpart 44.3.

(k) Paragraphs (d) and (f) of this clause do not apply to the following subcontracts, which were evaluated during negotiations:

(End of Clause)

I.5 FAR 52.244-2 Alternate II Subcontracts (Alternate II) (Aug 1998)

(f)(2) If the Contractor has an approved purchasing system and consent is not required under paragraph (c), (d), or (e) of this clause, the Contractor nevertheless shall notify the Contracting Officer reasonably in advance of entering into any (i) cost-plus-fixed-fee subcontract, or (ii) fixed-price subcontract that exceeds either the simplified acquisition threshold or 5 percent of the total estimated cost of this contract. The notification shall include the information required by paragraphs (f)(1)(i) through (f)(1)(iv) of this clause.

(End of Alternate)

I.6 FAR 52.244-6 Subcontracts for Commercial Items and Commercial Components (May 2002)

(a) *Definitions.* As used in this clause —

"Commercial item" has the meaning contained in the clause at 52.202-1, Definitions.

"Subcontract" includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

(c)(1) The Contractor shall insert the following clauses in subcontracts for commercial items:

(i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$500,000 (\$1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(ii) 52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).

(iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212(a));

(iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUNE 1998) (29 U.S.C. 793).

(v) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (JUNE 2000) (46 U.S.C. Appx 1241) (flowdown not required for subcontracts awarded beginning May 1, 1996).

(2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

(End of clause)

I.9 HHSAR 352.270-1 Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities (Jan 2001)

The Contractor agrees as follows:

(a) Planning. The Contractor will develop a plan to assure that any meeting, conference, or seminar held pursuant to this contract will meet or exceed the minimum accessibility standards set forth in 28 CFR 36.101-36.500 and Appendix A: ADA Accessibility Guidelines (ADAAG). The plan shall be submitted to the project officer for approval prior to initiating action. (A consolidated or master plan for contracts requiring numerous meetings, conferences, or seminars may be submitted in lieu of separate plans.)

(b) Facilities. Any facility to be utilized for meetings, conferences, or seminars in performance of this contract shall be in compliance with 28 CFR 36.101-36.500 and Appendix A. The Contractor shall determine, by an on-site inspection, that the facility meets these requirements.

(1) Parking. Parking shall be in compliance with 28 CFR 36.101-36.500 and Appendix A.

(2) Entrances. Entrances shall be in compliance with 28 CFR 36.101-36.500 and Appendix A.

(3) Meeting Rooms. Meeting rooms, including seating arrangements, shall be in compliance with 28 CFR 36.101-36.500 and Appendix A. In addition, stages, speaker platforms, etc. which are to be used by persons in wheelchairs must be accessible by ramps or lifts. When used, the ramp may not necessarily be independently negotiable if space does not permit. However, any slope over 1:12 must be approved by the Project Officer and the Contractor must provide assistance to negotiate access to the stage or platform.

(4) Restrooms. Restrooms shall be in compliance with 28 CFR 36.101-36.500 and Appendix A.

(5) Eating Facilities. Eating facilities in the meeting facility must also comply with 28 CFR 36.101-36.500 and Appendix A.

(6) Overnight Facilities. If overnight accommodations are required, the facility providing the overnight accommodations shall also comply with 28 CFR 36.101-36.500 and Appendix A.

(7) Water Fountains. Water fountains shall comply with 28 CFR 36.101-36.500 and Appendix A.

(8) Telephones. Public telephones shall comply with 28 CFR 36.101-36.500 and Appendix A.

(c) Provisions of Services for Attendees with Sensory Impairments.

(1) The Contractor, in planning the meeting, conference, or seminar, shall include in all announcements and other materials pertaining to the meeting, conference, or seminar a notice indicating that services will be made available to persons with sensory impairments attending the meeting, if requested within five (5) days of the date of the meeting, conference, or seminar. The announcement(s) and other material(s) shall indicate that persons with sensory impairments may contact a specific person(s), at a specific address and phone number(s), to make their service requirements known. The phone number(s) shall include a telecommunication device for the deaf (TDD).

(2) The Contractor shall provide, at no additional cost to the individual, those services required by persons with sensory impairments to insure their complete participation in the meeting, conference, or seminar.

(3) As a minimum, when requested in advance, the Contractor shall provide the following services:

(i) For persons with hearing impairments, qualified interpreters. Also, the meeting rooms will be adequately illuminated so signing by interpreters can be easily seen.

(ii) For persons with vision impairments, readers and/or cassette materials, as necessary, to enable full participation. Also, meeting rooms will be adequately illuminated.

(iii) Agenda and other conference material(s) shall be translated into a usable form for persons with sensory impairments. Readers, braille translations, large print text, and/or tape recordings are all acceptable. These materials shall be available to individuals with sensory impairments upon their arrival.

(4) The Contractor is responsible for making a reasonable effort to ascertain the number of individuals with sensory impairments who plan to attend the meeting, conference, or seminar. However, if it can be determined that there will be no person with sensory impairment in attendance, the provision of those services under paragraph (c) of this clause for the nonrepresented group, or groups, is not required.

(End of clause)

Section J - List Of Attachments

- J.1** Reference List
- J.2** Contractor Performance Report (Cost Reimbursement)
- J.3** Protection of Human Subjects, Assurance Identification/IRB Certification/Declaration of Exemption
- J.4** Standard Form 294, Subcontracting Report for Individual Contracts
- J.5** Standard Form 295, Summary Subcontract Report.

ORDER FOR SUPPLIES OR SERVICES

PAGE OF PAGES

1 13

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER 08/29/2012		2. CONTRACT NO. (If any) 254-2012-M-53230		6. SHIP TO: a. NAME OF CONSIGNEE DHHS PHS CDC NIOSH ALOSH				
3. ORDER NO. 5. ISSUING OFFICE (Address correspondence to) Ctrs for Disease Control & Prevention (Pgh) Acquisition & Assistance Field Branch PO Box 18070, 626 Cochran's Mill Rd Pittsburgh, PA 15236-0070		4. REQUISITION/REFERENCE NO. 000HCCCH-2012-48887		b. STREET ADDRESS 1095 Willowdale Road				
				c. CITY Morgantown				
				d. STATE WV				
				e. ZIP CODE 26505-2888				
7. TO: a. NAME OF CONTRACTOR RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK		DUNS NUMBER: 038633251		f. SHIP VIA				
				8. TYPE OF ORDER				
b. COMPANY NAME		<input checked="" type="checkbox"/> a. PURCHASE REFERENCE YOUR:			<input type="checkbox"/> b. DELIVERY			
c. STREET ADDRESS 402 CROFTS HALL		Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.			Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above- numbered contract.			
d. CITY BUFFALO		e. STATE NY	f. ZIP CODE 14260-0001	9. ACCOUNTING AND APPROPRIATION DATA 927ZKEC 2555 2012 75-12-0953 5611PH1101				
10. REQUISITIONING OFFICE HCCCH		11. BUSINESS CLASSIFICATION (Check appropriate box(es))						
<input type="checkbox"/> a. SMALL		<input checked="" type="checkbox"/> b. OTHER THAN SMALL		<input type="checkbox"/> c. DISADVANTAGED		<input type="checkbox"/> d. WOMEN-OWNED		
12. F.O.B. POINT Destination		14. GOVERNMENT B/L NO.		15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date)		16. DISCOUNT TERMS		
13. PLACE OF a. INSPECTION				07/31/2013		Net 30 Days		
17. SCHEDULE (See reverse for Rejections)								
ITEM NO. (a)	SUPPLIES OR SERVICES (b)		QUANTITY ORDERED (c)	UNI T (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)	
	INVOICES MUST CONTAIN THE CONTRACT NUMBER IN BLOCK 2, COMPANY DUNS NUMBER, AND TAX ID NUMBER IN ORDER TO ASSURE PROPER PAYMENT. SEND INVOICES TO ADDRESS SHOWN IN BLOCK 21. PAYMENT INQUIRIES MAY BE MADE BY CONTACTING THE FINANCIAL MANAGEMENT OFFICE AT 404-498-4050. "See Continuation Page"							
SEE BILLING INSTRUCTIONS ON REVERSE	18. SHIPPING POINT		19. GROSS SHIPPING WEIGHT		20. INVOICE NO.		\$51,778.00	17(h) TOT. (Cont. pages)
			21. MAIL INVOICE TO:					
	a. NAME Centers for Disease Control and Prevention (FMO)							
	b. STREET ADDRESS (or P.O. Box) PO Box 15580 404-718-8100						\$51,778.00	17(i) GRAND TOTAL
c. CITY Atlanta		d. STATE GA	e. ZIP CODE 303330080					
22. UNITED STATES OF AMERICA (Signature) ➤				23. NAME (Typed) Brance L. McCune, Jr.				
				TITLE: CONTRACTING/ORDERING OFFICER				

SUPPLEMENTAL INVOICING INFORMATION

If desired, this order (or a copy thereof) may be used by the Contractor as the Contractor's invoice, instead of a separate invoice, provided the following statement, (signed and dated) is on (or attached to) the order: "Payment is requested in the amount of \$ _____. No other invoice will be submitted." However, if the Contractor wishes to submit an invoice, the following information must be provided: contract number (if any), order number, item number(s), description of supplies or service, sizes, quantities, unit prices, and extended totals. Prepaid shipping costs will be indicated as a separate item on the invoice. Where shipping costs exceed \$10 (except for parcel post), the billing must be supported by a bill of lading or receipt. When several orders are invoiced to an ordering activity during the same billing period, consolidated periodic billings are encouraged.

RECEIVING REPORT

Quantity in the "Quantity Accepted" column on the face of this order has been inspected, accepted, received by me and conforms to contract. Items listed below have been rejected for the reasons indicated.

SHIPMENT NUMBER	PARTIAL		DATE RECEIVED	SIGNATURE OF AUTHORIZED U.S. GOV'T REP.	DATE
	FINAL				
TOTAL CONTAINERS	GROSS WEIGHT	RECEIVED AT		TITLE	

REPORT OF REJECTIONS

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	Analysis of CVD Biomarkers The purpose of this contract is to support the retrieval, shipment and analysis of frozen serum specimens collected as part of the Buffalo Cardio-metabolic Occupational Police Stress (BCOPS) Study. The BCOPS Study, conducted from 2004-2009 with 464 police officers, is a cross-sectional study exploring the association between work stress and subclinical cardiovascular disease (CVD). As part of the study's clinical examination, officers provided blood specimens to be frozen for future research purposes. The objectives of the project are to: 1) prepare, package and ship the blood specimens to the Laboratory for Clinical Biochemistry Research (LCBR) at the University of Vermont, 2) analyze the blood specimens following standardized laboratory protocols, (Endothelin-1, E-selectin and Vascular Cell Adhesion Molecule (VCAM), 3) perform appropriate quality control measurements, and 4) provide the analytic results to NIOSH for incorporation into the BCOPS Study database. Performance of these objectives will allow investigators to assess the following research questions: 1) are occupational stressors associated with these novel CVD biomarkers, and 2) are these CVD biomarkers associated with subclinical CVD? Please see Statement of Work for full description. Quarterly payments are authorized. "other functions" Line(s) Of Accounting: 927ZKEC 2555 2012 75-12-0953 5611PH1101 (b)(4)	1 Each	(b)(4)	

CLAUSES

52.203-3 Gratuities.

As prescribed in [3.202](#), insert the following clause:

GRATUITIES (APR 1984)

- (a) The right of the Contractor to proceed may be terminated by written notice if, after notice and hearing, the agency head or a designee determines that the Contractor, its agent, or another representative—
(1) Offered or gave a gratuity (e.g., an entertainment or gift) to an officer, official, or employee of the Government; and
(2) Intended, by the gratuity, to obtain a contract or favorable treatment under a contract.
(b) The facts supporting this determination may be reviewed by any court having lawful jurisdiction.
(c) If this contract is terminated under paragraph (a) of this clause, the Government is entitled—
(1) To pursue the same remedies as in a breach of the contract; and
(2) In addition to any other damages provided by law, to exemplary damages of not less than 3 nor more than 10 times the cost incurred by the Contractor in giving gratuities to the person concerned, as determined by the agency head or a designee. (This paragraph (c)(2) is applicable only if this contract uses money appropriated to the Department of Defense.)
(d) The rights and remedies of the Government provided in this clause shall not be exclusive and are in addition to any other rights and remedies provided by law or under this contract.

52.212-4 Contract Terms and Conditions—Commercial Items.

As prescribed in [12.301](#)(b)(3), insert the following clause:

CONTRACT TERMS AND CONDITIONS—COMMERCIAL ITEMS (FEB 2012)

- (a) *Inspection/Acceptance.* The Contractor shall only tender for acceptance those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or reperformance of nonconforming services at no increase in contract price. If repair/replacement or reperformance will not correct the defects or is not possible, the Government may seek an equitable price reduction or adequate consideration for acceptance of nonconforming supplies or services. The Government must exercise its post-acceptance rights—
(1) Within a reasonable time after the defect was discovered or should have been discovered; and
(2) Before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.
(b) *Assignment.* The Contractor or its assignee may assign its rights to receive payment due as a result of performance of this contract to a bank, trust company, or other financing institution, including any Federal lending agency in accordance with the Assignment of Claims Act ([31 U.S.C. 3727](#)). However, when a third party makes payment (e.g., use of the Governmentwide commercial purchase card), the Contractor may not assign its rights to receive payment under this contract.
(c) *Changes.* Changes in the terms and conditions of this contract may be made only by written agreement of the parties.
(d) *Disputes.* This contract is subject to the Contract Disputes Act of 1978, as amended ([41 U.S.C. 601-613](#)). Failure of the parties to this contract to reach agreement on any request for equitable adjustment,

claim, appeal or action arising under or relating to this contract shall be a dispute to be resolved in accordance with the clause at FAR [52.233-1](#), Disputes, which is incorporated herein by reference. The Contractor shall proceed diligently with performance of this contract, pending final resolution of any dispute arising under the contract.

(e) *Definitions.* The clause at FAR [52.202-1](#), Definitions, is incorporated herein by reference.

(f) *Excusable delays.* The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence such as, acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement of any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch, and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.

(g) *Invoice.*

(1) The Contractor shall submit an original invoice and three copies (or electronic invoice, if authorized) to the address designated in the contract to receive invoices. An invoice must include—

- (i) Name and address of the Contractor;
- (ii) Invoice date and number;
- (iii) Contract number, contract line item number and, if applicable, the order number;
- (iv) Description, quantity, unit of measure, unit price and extended price of the items delivered;
- (v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading;
- (vi) Terms of any discount for prompt payment offered;
- (vii) Name and address of official to whom payment is to be sent;
- (viii) Name, title, and phone number of person to notify in event of defective invoice; and
- (ix) Taxpayer Identification Number (TIN). The Contractor shall include its TIN on the invoice only if required elsewhere in this contract.

(x) Electronic funds transfer (EFT) banking information.

(A) The Contractor shall include EFT banking information on the invoice only if required elsewhere in this contract.

(B) If EFT banking information is not required to be on the invoice, in order for the invoice to be a proper invoice, the Contractor shall have submitted correct EFT banking information in accordance with the applicable solicitation provision, contract clause (e.g., [52.232-33](#), Payment by Electronic Funds Transfer—Central Contractor Registration, or [52.232-34](#), Payment by Electronic Funds Transfer—Other Than Central Contractor Registration), or applicable agency procedures.

(C) EFT banking information is not required if the Government waived the requirement to pay by EFT.

(2) Invoices will be handled in accordance with the Prompt Payment Act ([31 U.S.C. 3903](#)) and Office of Management and Budget (OMB) prompt payment regulations at 5 CFR Part 1315.

(h) *Patent indemnity.* The Contractor shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of the performance of this contract, provided the Contractor is reasonably notified of such claims and proceedings.

(i) *Payment.—*

(1) *Items accepted.* Payment shall be made for items accepted by the Government that have been delivered to the delivery destinations set forth in this contract.

- (2) *Prompt payment.* The Government will make payment in accordance with the Prompt Payment Act ([31 U.S.C. 3903](#)) and prompt payment regulations at 5 CFR Part 1315.
- (3) *Electronic Funds Transfer (EFT).* If the Government makes payment by EFT, see [52.212-5\(b\)](#) for the appropriate EFT clause.
- (4) *Discount.* In connection with any discount offered for early payment, time shall be computed from the date of the invoice. For the purpose of computing the discount earned, payment shall be considered to have been made on the date which appears on the payment check or the specified payment date if an electronic funds transfer payment is made.
- (5) *Overpayments.* If the Contractor becomes aware of a duplicate contract financing or invoice payment or that the Government has otherwise overpaid on a contract financing or invoice payment, the Contractor shall—
- (i) Remit the overpayment amount to the payment office cited in the contract along with a description of the overpayment including the—
 - (A) Circumstances of the overpayment (e.g., duplicate payment, erroneous payment, liquidation errors, date(s) of overpayment);
 - (B) Affected contract number and delivery order number, if applicable;
 - (C) Affected contract line item or subline item, if applicable; and
 - (D) Contractor point of contact.
 - (ii) Provide a copy of the remittance and supporting documentation to the Contracting Officer.
- (6) *Interest.*
- (i) All amounts that become payable by the Contractor to the Government under this contract shall bear simple interest from the date due until paid unless paid within 30 days of becoming due. The interest rate shall be the interest rate established by the Secretary of the Treasury as provided in Section 611 of the Contract Disputes Act of 1978 (Public Law 95-563), which is applicable to the period in which the amount becomes due, as provided in (i)(6)(v) of this clause, and then at the rate applicable for each six-month period as fixed by the Secretary until the amount is paid.
 - (ii) The Government may issue a demand for payment to the Contractor upon finding a debt is due under the contract.
 - (iii) *Final decisions.* The Contracting Officer will issue a final decision as required by [33.211](#) if—
 - (A) The Contracting Officer and the Contractor are unable to reach agreement on the existence or amount of a debt within 30 days;
 - (B) The Contractor fails to liquidate a debt previously demanded by the Contracting Officer within the timeline specified in the demand for payment unless the amounts were not repaid because the Contractor has requested an installment payment agreement; or
 - (C) The Contractor requests a deferment of collection on a debt previously demanded by the Contracting Officer (see [32.607-2](#)).
 - (iv) If a demand for payment was previously issued for the debt, the demand for payment included in the final decision shall identify the same due date as the original demand for payment.
 - (v) Amounts shall be due at the earliest of the following dates:
 - (A) The date fixed under this contract.
 - (B) The date of the first written demand for payment, including any demand for payment resulting from a default termination.
 - (vi) The interest charge shall be computed for the actual number of calendar days involved beginning on the due date and ending on—
 - (A) The date on which the designated office receives payment from the Contractor;
 - (B) The date of issuance of a Government check to the Contractor from which an amount otherwise payable has been withheld as a credit against the contract debt; or

- (C) The date on which an amount withheld and applied to the contract debt would otherwise have become payable to the Contractor.
- (vii) The interest charge made under this clause may be reduced under the procedures prescribed in [32.608-2](#) of the Federal Acquisition Regulation in effect on the date of this contract.
- (j) *Risk of loss.* Unless the contract specifically provides otherwise, risk of loss or damage to the supplies provided under this contract shall remain with the Contractor until, and shall pass to the Government upon:
- (1) Delivery of the supplies to a carrier, if transportation is f.o.b. origin; or
- (2) Delivery of the supplies to the Government at the destination specified in the contract, if transportation is f.o.b. destination.
- (k) *Taxes.* The contract price includes all applicable Federal, State, and local taxes and duties.
- (l) *Termination for the Government's convenience.* The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.
- (m) *Termination for cause.* The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.
- (n) *Title.* Unless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession.
- (o) *Warranty.* The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract.
- (p) *Limitation of liability.* Except as otherwise provided by an express warranty, the Contractor will not be liable to the Government for consequential damages resulting from any defect or deficiencies in accepted items.
- (q) *Other compliances.* The Contractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance under this contract.
- (r) *Compliance with laws unique to Government contracts.* The Contractor agrees to comply with [31 U.S.C. 1352](#) relating to limitations on the use of appropriated funds to influence certain Federal contracts; [18 U.S.C. 431](#) relating to officials not to benefit; [40 U.S.C. 3701](#), et seq., Contract Work Hours and Safety Standards Act; [41 U.S.C. 51-58](#), Anti-Kickback Act of 1986; [41 U.S.C. 265](#) and [10 U.S.C. 2409](#) relating to whistleblower protections; [49 U.S.C. 40118](#), Fly American; and [41 U.S.C. 423](#) relating to procurement integrity.

(s) *Order of precedence.* Any inconsistencies in this solicitation or contract shall be resolved by giving precedence in the following order:

- (1) The schedule of supplies/services.
- (2) The Assignments, Disputes, Payments, Invoice, Other Compliances, and Compliance with Laws Unique to Government Contracts paragraphs of this clause.
- (3) The clause at [52.212-5](#).
- (4) Addenda to this solicitation or contract, including any license agreements for computer software.
- (5) Solicitation provisions if this is a solicitation.
- (6) Other paragraphs of this clause.
- (7) The [Standard Form 1449](#).
- (8) Other documents, exhibits, and attachments.
- (9) The specification.

(t) Central Contractor Registration (CCR).

(1) Unless exempted by an addendum to this contract, the Contractor is responsible during performance and through final payment of any contract for the accuracy and completeness of the data within the CCR database, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. To remain registered in the CCR database after the initial registration, the Contractor is required to review and update on an annual basis from the date of initial registration or subsequent updates its information in the CCR database to ensure it is current, accurate and complete. Updating information in the CCR does not alter the terms and conditions of this contract and is not a substitute for a properly executed contractual document.

(2)(i) If a Contractor has legally changed its business name, "doing business as" name, or division name (whichever is shown on the contract), or has transferred the assets used in performing the contract, but has not completed the necessary requirements regarding novation and change-of-name agreements in FAR [Subpart 42.12](#), the Contractor shall provide the responsible Contracting Officer a minimum of one business day's written notification of its intention to (A) change the name in the CCR database; (B) comply with the requirements of [Subpart 42.12](#); and (C) agree in writing to the timeline and procedures specified by the responsible Contracting Officer.

The Contractor must provide with the notification sufficient documentation to support the legally changed name.

(ii) If the Contractor fails to comply with the requirements of paragraph (t)(2)(i) of this clause, or fails to perform the agreement at paragraph (t)(2)(i)(C) of this clause, and, in the absence of a properly executed novation or change-of-name agreement, the CCR information that shows the Contractor to be other than the Contractor indicated in the contract will be considered to be incorrect information within the meaning of the "Suspension of Payment" paragraph of the electronic funds transfer (EFT) clause of this contract.

(3) The Contractor shall not change the name or address for EFT payments or manual payments, as appropriate, in the CCR record to reflect an assignee for the purpose of assignment of claims (see [Subpart 32.8](#), Assignment of Claims). Assignees shall be separately registered in the CCR database. Information provided to the Contractor's CCR record that indicates payments, including those made by EFT, to an ultimate recipient other than that Contractor will be considered to be incorrect information within the meaning of the "Suspension of payment" paragraph of the EFT clause of this contract.

(4) Offerors and Contractors may obtain information on registration and annual confirmation requirements via CCR accessed through <https://www.acquisition.gov> or by calling 1-888-227-2423 or 269-961-5757.

(End of clause)

52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items.

As prescribed in [12.301\(b\)\(4\)](#), insert the following clause:

CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS—
COMMERCIAL ITEMS (JUL 2012)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

- (1) [52.222-50](#), Combating Trafficking in Persons (Feb 2009) ([22 U.S.C. 7104\(g\)](#)).
____ Alternate I (Aug 2007) of [52.222-50](#) ([22 U.S.C. 7104\(g\)](#)).
- (2) [52.233-3](#), Protest After Award (AUG 1996) ([31 U.S.C. 3553](#)).
- (3) [52.233-4](#), Applicable Law for Breach of Contract Claim (Oct 2004) (Pub. L. 108-77, 108-78).
- (b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

- x (1) [52.203-6](#), Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) ([41 U.S.C. 253g](#) and [10 U.S.C. 2402](#)).
- ____ (2) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Apr 2010) (Pub. L. 110-252, Title VI, Chapter 1 ([41 U.S.C. 251 note](#))).
- ____ (3) [52.203-15](#), Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (June 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
- ____ (4) [52.204-10](#), Reporting Executive Compensation and First-Tier Subcontract Awards (Feb 2012) (Pub. L. 109-282) ([31 U.S.C. 6101 note](#)).
- ____ (5) [52.204-11](#), American Recovery and Reinvestment Act—Reporting Requirements (Jul 2010) (Pub. L. 111-5).
- x (6) [52.209-6](#), Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Dec 2010) ([31 U.S.C. 6101 note](#)).
- ____ (7) [52.209-9](#), Updates of Publicly Available Information Regarding Responsibility Matters (Feb 2012) ([41 U.S.C. 2313](#)).
- ____ (8) [52.209-10](#), Prohibition on Contracting with Inverted Domestic Corporations (May 2012) (section 738 of Division C of Pub. L. 112-74, section 740 of Division C of Pub. L. 111-117, section 743 of Division D of Pub. L. 111-8, and section 745 of Division D of Pub. L. 110-161).
- ____ (9) [52.219-3](#), Notice of HUBZone Set-Aside or Sole-Source Award (Nov 2011) ([15 U.S.C. 657a](#)).
- ____ (10) [52.219-4](#), Notice of Price Evaluation Preference for HUBZone Small Business Concerns (JAN 2011) (if the offeror elects to waive the preference, it shall so indicate in its offer) ([15 U.S.C. 657a](#)).
- ____ (11) [Reserved]
- x (12)(i) [52.219-6](#), Notice of Total Small Business Set-Aside (Nov 2011) ([15 U.S.C. 644](#)).
 - ____ (ii) Alternate I (Nov 2011).
 - ____ (iii) Alternate II (Nov 2011).
- ____ (13)(i) [52.219-7](#), Notice of Partial Small Business Set-Aside (June 2003) ([15 U.S.C. 644](#)).
 - ____ (ii) Alternate I (Oct 1995) of [52.219-7](#).

- (iii) Alternate II (Mar 2004) of [52.219-7](#).
- (14) [52.219-8](#), Utilization of Small Business Concerns (Jan 2011) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)).
- (15)(i) [52.219-9](#), Small Business Subcontracting Plan (Jan 2011) ([15 U.S.C. 637\(d\)\(4\)](#)).
- (ii) Alternate I (Oct 2001) of [52.219-9](#).
- (iii) Alternate II (Oct 2001) of [52.219-9](#).
- (iv) Alternate III (Jul 2010) of [52.219-9](#).
- (16) [52.219-13](#), Notice of Set-Aside of Orders (Nov 2011) ([15 U.S.C. 644\(r\)](#)).
- (17) [52.219-14](#), Limitations on Subcontracting (Nov 2011) ([15 U.S.C. 637\(a\)\(14\)](#)).
- (18) [52.219-16](#), Liquidated Damages—Subcon-tracting Plan (Jan 1999) ([15 U.S.C. 637\(d\)\(4\)\(F\)\(i\)](#)).
- (19)(i) [52.219-23](#), Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (Oct 2008) ([10 U.S.C. 2323](#)) (if the offeror elects to waive the adjustment, it shall so indicate in its offer).
- (ii) Alternate I (June 2003) of [52.219-23](#).
- (20) [52.219-25](#), Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting (Dec 2010) (Pub. L. 103-355, section 7102, and [10 U.S.C. 2323](#)).
- (21) [52.219-26](#), Small Disadvantaged Business Participation Program— Incentive Subcontracting (Oct 2000) (Pub. L. 103-355, section 7102, and [10 U.S.C. 2323](#)).
- (22) [52.219-27](#), Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Nov 2011) ([15 U.S.C. 657 f](#)).
- (23) [52.219-28](#), Post Award Small Business Program Rerepresentation (Apr 2012) ([15 U.S.C. 632\(a\)\(2\)](#)).
- (24) [52.219-29](#), Notice of Set-Aside for Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (Apr 2012) ([15 U.S.C. 637\(m\)](#)).
- (25) [52.219-30](#), Notice of Set-Aside for Women-Owned Small Business (WOSB) Concerns Eligible Under the WOSB Program (Apr 2012) ([15 U.S.C. 637\(m\)](#)).
- (26) [52.222-3](#), Convict Labor (June 2003) (E.O. 11755).
- (27) [52.222-19](#), Child Labor—Cooperation with Authorities and Remedies (Mar 2012) (E.O. 13126).
- (28) [52.222-21](#), Prohibition of Segregated Facilities (Feb 1999).
- (29) [52.222-26](#), Equal Opportunity (Mar 2007) (E.O. 11246).
- (30) [52.222-35](#), Equal Opportunity for Veterans (Sep 2010) ([38 U.S.C. 4212](#)).
- (31) [52.222-36](#), Affirmative Action for Workers with Disabilities (Oct 2010) ([29 U.S.C. 793](#)).
- (32) [52.222-37](#), Employment Reports on Veterans (SEP 2010) (38 U.S.C. 4212).
- (33) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
- (34) [52.222-54](#), Employment Eligibility Verification (JUL 2012). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in [22.1803](#).)
- (35)(i) [52.223-9](#), Estimate of Percentage of Recovered Material Content for EPA—Designated Items (May 2008) ([42 U.S.C. 6962\(c\)\(3\)\(A\)\(ii\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
 - (ii) Alternate I (May 2008) of [52.223-9](#) ([42 U.S.C. 6962\(i\)\(2\)\(C\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- (36) [52.223-15](#), Energy Efficiency in Energy-Consuming Products (DEC 2007) ([42 U.S.C. 8259b](#)).
- (37)(i) [52.223-16](#), IEEE 1680 Standard for the Environmental Assessment of Personal Computer Products (DEC 2007) (E.O. 13423).
 - (ii) Alternate I (DEC 2007) of [52.223-16](#).
- (38) [52.223-18](#), Encouraging Contractor Policies to Ban Text Messaging While Driving (AUG 2011) (E.O. 13513).

- x_ (39) [52.225-1](#), Buy American Act—Supplies (Feb 2009) ([41 U.S.C. 10a-10d](#)).
- (40)(i) [52.225-3](#), Buy American Act—Free Trade Agreements—Israeli Trade Act (May 2012) ([41 U.S.C. chapter 83](#), [19 U.S.C. 3301](#) note, [19 U.S.C. 2112](#) note, [19 U.S.C. 3805](#) note, [19 U.S.C. 4001](#) note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, and 112-42).
 - (ii) Alternate I (Mar 2012) of [52.225-3](#).
 - (iii) Alternate II (Mar 2012) of [52.225-3](#).
 - (iv) Alternate III (Mar 2012) of [52.225-3](#).
- (41) [52.225-5](#), Trade Agreements (MAY 2012) ([19 U.S.C. 2501](#), et seq., [19 U.S.C. 3301](#) note).
- x_ (42) [52.225-13](#), Restrictions on Certain Foreign Purchases (June 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
- (43) [52.226-4](#), Notice of Disaster or Emergency Area Set-Aside (Nov 2007) ([42 U.S.C. 5150](#)).
- (44) [52.226-5](#), Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) ([42 U.S.C. 5150](#)).
- (45) [52.232-29](#), Terms for Financing of Purchases of Commercial Items (Feb 2002) ([41 U.S.C. 255\(f\)](#), [10 U.S.C. 2307\(f\)](#)).
- (46) [52.232-30](#), Installment Payments for Commercial Items (Oct 1995) ([41 U.S.C. 255\(f\)](#), [10 U.S.C. 2307\(f\)](#)).
- x_ (47) [52.232-33](#), Payment by Electronic Funds Transfer—Central Contractor Registration (Oct 2003) ([31 U.S.C. 3332](#)).
- (48) [52.232-34](#), Payment by Electronic Funds Transfer—Other than Central Contractor Registration (May 1999) ([31 U.S.C. 3332](#)).
- (49) [52.232-36](#), Payment by Third Party (Feb 2010) ([31 U.S.C. 3332](#)).
- (50) [52.239-1](#), Privacy or Security Safeguards (Aug 1996) ([5 U.S.C. 552a](#)).
- (51)(i) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. Appx. 1241\(b\)](#) and [10 U.S.C. 2631](#)).
 - (ii) Alternate I (Apr 2003) of [52.247-64](#).
- (c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:
[Contracting Officer check as appropriate.]
 - (1) [52.222-41](#), Service Contract Act of 1965 (Nov 2007) ([41 U.S.C. 351](#), et seq.).
 - (2) [52.222-42](#), Statement of Equivalent Rates for Federal Hires (May 1989) ([29 U.S.C. 206](#) and [41 U.S.C. 351](#), et seq.).
 - (3) [52.222-43](#), Fair Labor Standards Act and Service Contract Act—Price Adjustment (Multiple Year and Option Contracts) (Sep 2009) ([29 U.S.C. 206](#) and [41 U.S.C. 351](#), et seq.).
 - (4) [52.222-44](#), Fair Labor Standards Act and Service Contract Act—Price Adjustment (Sep 2009) ([29 U.S.C. 206](#) and [41 U.S.C. 351](#), et seq.).
 - (5) [52.222-51](#), Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment—Requirements (Nov 2007) ([41 U.S.C. 351](#), et seq.).
 - (6) [52.222-53](#), Exemption from Application of the Service Contract Act to Contracts for Certain Services—Requirements (Feb 2009) ([41 U.S.C. 351](#), et seq.).
 - (7) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (Mar 2009) (Pub. L. 110-247).
 - (8) [52.237-11](#), Accepting and Dispensing of \$1 Coin (Sept 2008) ([31 U.S.C. 5112\(p\)\(1\)](#)).

- (d) *Comptroller General Examination of Record.* The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at [52.215-2](#), Audit and Records—Negotiation.
- (1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.
- (2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR [Subpart 4.7](#), Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.
- (3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.
- (e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—
- (i) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Apr 2010) (Pub. L. 110-252, Title VI, Chapter 1 ([41 U.S.C. 251 note](#))).
- (ii) [52.219-8](#), Utilization of Small Business Concerns (Dec 2010) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$650,000 (\$1.5 million for construction of any public facility), the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.
- (iii) [Reserved]
- (iv) [52.222-26](#), Equal Opportunity (Mar 2007) (E.O. 11246).
- (v) [52.222-35](#), Equal Opportunity for Veterans (Sep 2010) ([38 U.S.C. 4212](#)).
- (vi) [52.222-36](#), Affirmative Action for Workers with Disabilities (Oct 2010) ([29 U.S.C. 793](#)).
- (vii) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause [52.222-40](#).
- (viii) [52.222-41](#), Service Contract Act of 1965 (Nov 2007) ([41 U.S.C. 351](#), et seq.).
- (ix) [52.222-50](#), Combating Trafficking in Persons (Feb 2009) ([22 U.S.C. 7104\(g\)](#)).
- _____ Alternate I (Aug 2007) of [52.222-50](#) ([22 U.S.C. 7104\(g\)](#)).
- (x) [52.222-51](#), Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (Nov 2007) ([41 U.S.C. 351](#), et seq.).
- (xi) [52.222-53](#), Exemption from Application of the Service Contract Act to Contracts for Certain Services-Requirements (Feb 2009) ([41 U.S.C. 351](#), et seq.).
- (xii) [52.222-54](#), Employment Eligibility Verification (JUL 2012).
- (xiii) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (Mar 2009) (Pub. L. 110-247). Flow down required in accordance with paragraph (e) of FAR clause [52.226-6](#).
- (xiv) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. Appx. 1241\(b\)](#) and [10 U.S.C. 2631](#)). Flow down required in accordance with paragraph (d) of FAR clause [52.247-64](#).

(2) While not required, the contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(END OF CLAUSE)

From: Andrew, Michael E. (CDC/NIOSH/HELD/BB)
Sent: Mon, 18 Nov 2019 19:42:44 +0000
To: Goedel, Kathleen E. (CDC/NIOSH/OD); Siegel, Paul D. (CDC/NIOSH/HELD)
Subject: RE: DUA - NIOSH/HELD and SUNY Buffalo - Buffalo Police Stress Dataset
Attachments: DUA attach 2 (1).pdf, DUA BCOPS Table 1.pdf, CDC-NIOSH DUA MEA revisions
11-18-19.pdf

Hello Kathleen & Paul,

I revised the BCOPS DUA to include the details suggested by Kathleen. As you can see the whole thing is complex. (b)(5)

(b)(5) I will need to run this by John Violanti before it goes on through the process but wanted your opinion before sending it to him.

Let me know what you think.

Regards,

Mike

Michael E Andrew, Ph.D.
Branch Chief
BioAnalytics Branch
Health Effects Laboratory Division
CDC/NIOSH
Phone: 304.285.6189
Email: mandrew@cdc.gov

From: Goedel, Kathleen E. (CDC/NIOSH/OD) <keg2@cdc.gov>
Sent: Thursday, October 3, 2019 11:40 AM
To: Siegel, Paul D. (CDC/NIOSH/HELD) <pds3@cdc.gov>; Andrew, Michael E. (CDC/NIOSH/HELD/BB) <mta6@cdc.gov>
Subject: FW: DUA - NIOSH/HELD and SUNY Buffalo - Buffalo Police Stress Dataset

Paul and Michael,

Attached are my initial comments for this draft DUA between NIOSH/HELD and SUNY Buffalo. Bill Brinkley has asked to see all DUAs so once I receive your responses, I will pass the documents to him for review.

Kathleen

From: Siegel, Paul D. (CDC/NIOSH/HELD) <pds3@cdc.gov>
Sent: Wednesday, October 2, 2019 7:05 AM
To: Goedel, Kathleen E. (CDC/NIOSH/OD) <keg2@cdc.gov>
Cc: Andrew, Michael E. (CDC/NIOSH/HELD/BB) <mta6@cdc.gov>
Subject: FW: DUA

Kathleen,
Can you review these DUAs.
(Would you or Don sign off on these for NIOSH?)
Thanks,
Paul

Paul D. Siegel, Ph.D.
Associate Director for Science
CAPT, USPHS
HELD/NIOSH/CDC
1095 Willowdale Rd.
Morgantown, WV 26505-2888
Phone: 304-285-5855; Fax: 304-285-6126

From: Andrew, Michael E. (CDC/NIOSH/HELD/BB) <mta6@cdc.gov>
Sent: Tuesday, October 1, 2019 3:56 PM
To: Siegel, Paul D. (CDC/NIOSH/HELD) <pds3@cdc.gov>
Subject: FW: DUA

Hello Paul,

Here is a DUA that is now required by SUNY Buffalo for our use of the BCOPS data. It looks pretty straightforward to me. I assume it has to be reviewed by Kathleen Goedel before Don can sign it.

Thanks,

Mike

From: Violanti, John <violanti@buffalo.edu>
Sent: Tuesday, October 1, 2019 1:23 PM
To: Andrew, Michael E. (CDC/NIOSH/HELD/BB) <mta6@cdc.gov>
Subject: DUA

Hi Mike:
I have attached the DUA for BCOPS data use. If this is approved by NIOSH, please return. If these are changes, UB will have to review once more and then sign.
John

From: Andrew, Michael E. (CDC/NIOSH/HELD/BB)
Sent: Thu, 5 Dec 2019 14:10:26 +0000
To: Goedel, Kathleen E. (CDC/NIOSH/OD); Siegel, Paul D. (CDC/NIOSH/HELD)
Subject: RE: DUA - NIOSH/HELD and SUNY Buffalo - Buffalo Police Stress Dataset

Hi Kathleen,

Thanks. I agree.

Mike

From: Goedel, Kathleen E. (CDC/NIOSH/OD) <keg2@cdc.gov>
Sent: Thursday, December 5, 2019 9:09 AM
To: Andrew, Michael E. (CDC/NIOSH/HELD/BB) <mta6@cdc.gov>; Siegel, Paul D. (CDC/NIOSH/HELD) <pds3@cdc.gov>
Subject: RE: DUA - NIOSH/HELD and SUNY Buffalo - Buffalo Police Stress Dataset

Thank you for the revised documents. I anticipate Bill having additional questions so I've shared the revised drafts with him for review. I thought it might be more efficient to address all of NIOSH's questions before reconnecting with John Violanti. I'll let you know when I have received Bill's response.

From: Andrew, Michael E. (CDC/NIOSH/HELD/BB) <mta6@cdc.gov>
Sent: Monday, November 18, 2019 2:43 PM
To: Goedel, Kathleen E. (CDC/NIOSH/OD) <keg2@cdc.gov>; Siegel, Paul D. (CDC/NIOSH/HELD) <pds3@cdc.gov>
Subject: RE: DUA - NIOSH/HELD and SUNY Buffalo - Buffalo Police Stress Dataset

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Branch Chief
BioAnalytics Branch
Health Effects Laboratory Division
CDC/NIOSH
Phone: 304.285.6189

Email: mandrew@cdc.gov

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Subject: FW: DUA - NIOSH/HELD and SUNY Buffalo - Buffalo Police Stress Dataset

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Sent: Wednesday, October 2, 2019 7:05 AM
To: Goedel, Kathleen E. (CDC/NIOSH/OD) <keg2@cdc.gov>
Cc: Andrew, Michael E. (CDC/NIOSH/HELD/BB) <mta6@cdc.gov>
Subject: FW: DUA

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(Would you or Don sign off on these for NIOSH?)
Thanks,
Paul

Paul D. Siegel, Ph.D.
Associate Director for Science
CAPT, USPHS
HELD/NIOSH/CDC
1095 Willowdale Rd.
Morgantown, WV 26505-2888
Phone: 304-285-5855; Fax: 304-285-6126

From: Andrew, Michael E. (CDC/NIOSH/HELD/BB) <mta6@cdc.gov>
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Sent: Tuesday, October 1, 2019 1:23 PM
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Subject: DUA

Hi Mike:

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John

From: Goedel, Kathleen E. (CDC/NIOSH/OD)
Sent: Wed, 5 Feb 2020 16:19:20 +0000
To: Andrew, Michael E. (CDC/NIOSH/HELD/BB)
Cc: Siegel, Paul D. (CDC/NIOSH/HELD)
Subject: FW: DUA - NIOSH/HELD and SUNY Buffalo - Buffalo Police Stress Dataset
Attachments: DUA attach 2 (1).pdf, CDC-NIOSH DUA MEA revisions 11-18-19.pdf, DUA BCOPS Table 1.pdf

Michael,

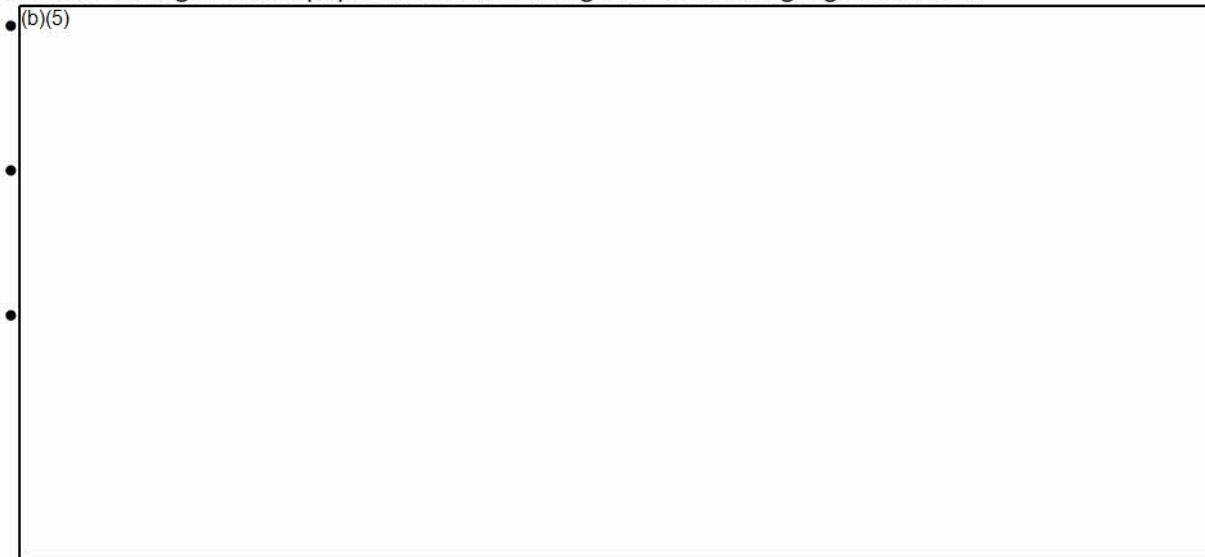
Sorry for the delay in responding. Attached and below are edits and comments from Alice, the NIOSH IT team, and me for the proposed DUA with SUNY Buffalo. Let me know if you would like to discuss any of these changes in more detail.

Kathleen

From: Momin, Nabila (CDC/NIOSH/OD/ODDM) (CTR) <pwg8@cdc.gov>
Sent: Friday, December 27, 2019 11:10 AM
To: Brinkley, William (Bill) (CDC/NIOSH/OD/ODDM) <gjy2@cdc.gov>
Subject: RE: DUA - NIOSH/HELD and SUNY Buffalo - Buffalo Police Stress Dataset

Hi Bill,

There are a few things follow-up questions I have along with the one highlighted below:



Please let me know if you have any questions.

Thank you,

Nabila Momin

From: Kelley, Alice A. (CDC/OCOO/OGC) <amk5@cdc.gov>
Sent: Thursday, December 26, 2019 2:57 PM
To: Goedel, Kathleen E. (CDC/NIOSH/OD) <keg2@cdc.gov>; Brinkley, William (Bill)
(CDC/NIOSH/OD/ODDM) <gjy2@cdc.gov>
Cc: McGolerick, Robert (CDC/OCOO/OGC) <bku7@cdc.gov>
Subject: RE: DUA - NIOSH/HELD and SUNY Buffalo - Buffalo Police Stress Dataset

Good afternoon, all. I have reviewed this agreement and its related attachments. (b)(5)

(b)(5)

(b)(5)

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I apologize for the formatting errors in this response – my laptop wants to go haywire today when I try to edit those. Please let me know if you would like to discuss this agreement with me.

Best regards, and happy holidays,
Alice Kelley
Alice A. Kelley
Senior Attorney
Department of Health and Human Services
Office of the General Counsel, Public Health Division
Centers for Disease Control and Prevention (CDC) Branch
5600 Fishers Lane, Room 4A53
Rockville, MD 20857
Telephone: (301) 443-0325
Fax: (301) 443-2639
Email: AKelley@cdc.gov

From: Andrew, Michael E. (CDC/NIOSH/HELD/BB) <mta6@cdc.gov>
Sent: Monday, November 18, 2019 2:43 PM
To: Goedel, Kathleen E. (CDC/NIOSH/OD) <keg2@cdc.gov>; Siegel, Paul D. (CDC/NIOSH/HELD) <pds3@cdc.gov>
Subject: RE: DUA - NIOSH/HELD and SUNY Buffalo - Buffalo Police Stress Dataset

Hello Kathleen & Paul,

I revised the BCOPS DUA to include the details suggested by Kathleen. As you can see the whole thing is complex

(b)(5) will need to run this by John Violanti before it goes on through the process but wanted your opinion before sending it to him.

Let me know what you think.

Regards,

Mike

Michael E Andrew, Ph.D.
Branch Chief
BioAnalytics Branch
Health Effects Laboratory Division
CDC/NIOSH
Phone: 304.285.6189
Email: mandrew@cdc.gov

From: Goedel, Kathleen E. (CDC/NIOSH/OD) <keg2@cdc.gov>
Sent: Thursday, October 3, 2019 11:40 AM
To: Siegel, Paul D. (CDC/NIOSH/HELD) <pds3@cdc.gov>; Andrew, Michael E. (CDC/NIOSH/HELD/BB) <mta6@cdc.gov>
Subject: FW: DUA - NIOSH/HELD and SUNY Buffalo - Buffalo Police Stress Dataset

Paul and Michael,

Attached are my initial comments for this draft DUA between NIOSH/HELD and SUNY Buffalo. Bill Brinkley has asked to see all DUAs so once I receive your responses, I will pass the documents to him for review.

Kathleen

From: Siegel, Paul D. (CDC/NIOSH/HELD) <pds3@cdc.gov>
Sent: Wednesday, October 2, 2019 7:05 AM
To: Goedel, Kathleen E. (CDC/NIOSH/OD) <keg2@cdc.gov>
Cc: Andrew, Michael E. (CDC/NIOSH/HELD/BB) <mta6@cdc.gov>
Subject: FW: DUA

Kathleen,
Can you review these DUAs.
(Would you or Don sign off on these for NIOSH?)
Thanks,
Paul

Paul D. Siegel, Ph.D.
Associate Director for Science
CAPT, USPHS
HELD/NIOSH/CDC
1095 Willowdale Rd.
Morgantown, WV 26505-2888
Phone: 304-285-5855; Fax: 304-285-6126

From: Andrew, Michael E. (CDC/NIOSH/HELD/BB) <mta6@cdc.gov>
Sent: Tuesday, October 1, 2019 3:56 PM
To: Siegel, Paul D. (CDC/NIOSH/HELD) <pds3@cdc.gov>
Subject: FW: DUA

Hello Paul,

Here is a DUA that is now required by SUNY Buffalo for our use of the BCOPS data. It looks pretty straightforward to me. I assume it has to be reviewed by Kathleen Goedel before Don can sign it.

Thanks,

Mike

From: Violanti, John <violanti@buffalo.edu>
Sent: Tuesday, October 1, 2019 1:23 PM
To: Andrew, Michael E. (CDC/NIOSH/HELD/BB) <mta6@cdc.gov>
Subject: DUA

Hi Mike:

I have attached the DUA for BCOPS data use. If this is approved by NIOSH, please return. If these are changes, UB will have to review once more and then sign.

John

