

**SOLICITATION, OFFER AND AWARD**

1. THIS CONTRACT IS A RATED ORDER UNDER OPAS (28 CFR 706) RATING PAGE OF PAGES  
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2. CONTRACT NUMBER: **BHSF2232009100061**      3. SOLICITATION NUMBER: **09-223-sol-00112**      4. TYPE OF SOLICITATION:  SEALED BID (FS)  NEGOTIATED (RFP)      5. DATE ISSUED: **09/23/09**      6. ACQUISITION/PURCHASE NUMBER: **See Schedule**

7. ISSUED BY: **DHHS/FDA/OAGS/DCGM**      CODE: **DCGM**      8. ADDRESS OFFER TO (if other than item 7):

DHHS/FDA/OAGS/DCGM  
ATTN: Tara Hobson  
5630 FISHERS LANE  
ROOM 2129, HFA-500  
ROCKVILLE MD 20857

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

**SOLICITATION**

9. Sealed offers to be opened on \_\_\_\_\_ at \_\_\_\_\_ o'clock in the \_\_\_\_\_ of \_\_\_\_\_ at the \_\_\_\_\_ in the \_\_\_\_\_ of \_\_\_\_\_.

CAUTION: Late Submissions, Modifications, and Withdrawals: See Section L, Provision No. 02.214-7 or 02.215-1. All offers are subject to all terms and conditions contained in this solicitation. (Hour) \_\_\_\_\_ (Date) \_\_\_\_\_

10. FOR INFORMATION CALL: **TARA (HOBSON)**      A. NAME

B. TELEPHONE (NO COLLECT CALLS)      C. E-MAIL ADDRESS: **tara.hobson@fda.hhs.gov**

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OFFER (Must be fully completed by offeror)

NOTE: Item 12 does not apply if the solicitation includes the provisions at 02.214-16, 02.215-16, 02.215-17, 02.215-18, 02.215-19, 02.215-20, 02.215-21, 02.215-22, 02.215-23, 02.215-24, 02.215-25, 02.215-26, 02.215-27, 02.215-28, 02.215-29, 02.215-30, 02.215-31, 02.215-32, 02.215-33, 02.215-34, 02.215-35, 02.215-36, 02.215-37, 02.215-38, 02.215-39, 02.215-40, 02.215-41, 02.215-42, 02.215-43, 02.215-44, 02.215-45, 02.215-46, 02.215-47, 02.215-48, 02.215-49, 02.215-50, 02.215-51, 02.215-52, 02.215-53, 02.215-54, 02.215-55, 02.215-56, 02.215-57, 02.215-58, 02.215-59, 02.215-60, 02.215-61, 02.215-62, 02.215-63, 02.215-64, 02.215-65, 02.215-66, 02.215-67, 02.215-68, 02.215-69, 02.215-70, 02.215-71, 02.215-72, 02.215-73, 02.215-74, 02.215-75, 02.215-76, 02.215-77, 02.215-78, 02.215-79, 02.215-80, 02.215-81, 02.215-82, 02.215-83, 02.215-84, 02.215-85, 02.215-86, 02.215-87, 02.215-88, 02.215-89, 02.215-90, 02.215-91, 02.215-92, 02.215-93, 02.215-94, 02.215-95, 02.215-96, 02.215-97, 02.215-98, 02.215-99, 02.215-100.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within \_\_\_\_\_ calendar days (90 calendar days unless a different period is invited 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 (See Section L, Clause No. 02.214-6)  10 CALENDAR DAYS (90)       30 CALENDAR DAYS (90)       60 CALENDAR DAYS (90)       90 CALENDAR DAYS (90)

14. ACKNOWLEDGEMENT OF AMENDMENTS (The offeror acknowledges receipt of amendments to the SOLICITATION for offers and related documents numbered and dated:

AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR: **HARVARD PILGRIM HEALTH CARE INC 116298**  
**HARVARD PILGRIM HEALTH CARE INC**  
**93 WORCESTER RD**  
**WELLESLEY MA 02481-3609**

15B. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER (Type or print): **Roberta Herman, MD**  
**Interim COO**

16. TELEPHONE NUMBER: AREA CODE \_\_\_\_\_ NUMBER \_\_\_\_\_ EXT. \_\_\_\_\_

17. SIGNATURE: *Roberta Herman*      18. OFFER DATE: **9.25.09**

19. ACCEPTED AS TO ITEMS NUMBERED \_\_\_\_\_      20. AMOUNT: **\$4,443,309.00**      21. ACCOUNTING AND APPROPRIATION: **See schedule**

22. AUTHORITY FOR USES OTHER THAN FULL AND OPEN COMPETITION:  10 U.S.C. 2304 (4) ( )       41 U.S.C. 203 (4) ( )      23. BUDGET BRANCH TO ADDRESS (SHOW IN IT) (If plus enter otherwise specified): \_\_\_\_\_

24. ADMINISTERED BY (if other than item 7): **See Schedule G**      CODE: **DCGM**      25. PAYMENT WILL BE MADE BY: **See Schedule G**      CODE: **7**

26. NAME OF CONTRACTING OFFICER (Type or print): **LEONARD D. GRANT**      27. UNITED STATES OF AMERICA: *Leonard D. Grant*      28. AWARD DATE: **9/25/09**

IMPORTANT - Award will be made on this Form, or on Standard Form 25, or by other authorized official within notice. AUTHORIZED FOR LOCAL REPRODUCTION. Reproduction is unlimited.

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NAME OF OFFEROR OR CONTRACTOR  
 HARVARD PILGRIM HEALTH CARE INC 116298

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
1	<p>Tax ID Number: 04-2452600                      DUNS Number: 071721088                      IDIQ CONTRACT FOR FIVE YEARS: (1) BASE YEAR PLUS (4) OPTION YEARS</p> <p>Efforts to Develop the Sentinel Initiative</p> <p>BASE YEAR: SEPTEMBER 23, 2009-SEPTEMBER 22, 2010                      OPTION YEAR ONE: SEPTEMBER 23, 2010-SEPTEMBER 22, 2011                      OPTION YEAR TWO: SEPTEMBER 23, 2011-SEPTEMBER 22, 2012                      OPTION YEAR THREE: SEPTEMBER 23, 2012-SEPTEMBER 22, 2013                      OPTION YEAR FOUR: SEPTEMBER 23, 2013-SEPTEMBER 22, 2014</p> <p>As consideration for the services described in Section C.1[b], "Scope of Work," the Government shall pay the Contractor the fixed price of \$4,443,309.00.</p> <p>Payment will be made on presentation of a proper invoice and in accordance with the following schedule:</p> <p>(b) (4) per month for the Coordinating Center.</p> <p>Admin Office:                      DHHS/FDA/OAGS/DCGM                      ATTN: Tara Hobson                      5630 FISHERS LANE                      ROOM 2129, HFA-500                      ROCKVILLE MD 20857</p> <p>Payment:                      DHHS/FDA/OAGS/DCGM                      ATTN:                      5630 FISHERS LANE                      ROOM 2129, HFA-531                      ROCKVILLE MD 20857</p> <p>FOB: Destination                      Period of Performance: 09/23/2009 to 09/22/2014</p> <p>Base Contract-                      Coordinating Center</p> <p>Detection and Analysis of Adverse Events related to Regulated Products in Automated Healthcare Data Efforts to Develop the Sentinel Initiative Continued ...</p>				(b) (4)

<b>CONTINUATION SHEET</b>	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE	OF
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NAME OF OFFEROR OR CONTRACTOR  
 HARVARD PILGRIM HEALTH CARE INC 116298

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT-PRICE (E)	AMOUNT (F)
	Obligated Amount: (b) (4) Requisition No: 1063529, 1065716, 1066313  Delivery Location Code: FDA FDA US Food and Drug Administration 5600 Fishers Lane Rockville MD 20857 US Amount: (b) (4) Accounting Info: 2009-6992990-252Z-D96025DD000MMS1 Appr. Yr.: 2009 CAN: 6992990 Object Class: 252Z CenterTag: D96025DD000MMS1 Funded: (b) (4)  Delivery Location Code: FDA FDA US Food and Drug Administration 5600 Fishers Lane Rockville MD 20857 US Amount: (b) (4) Accounting Info: 2009-69999NP-25AB-BM121ORA0001062 Appr. Yr.: 2009 CAN: 69999NP Object Class: 25AB CenterTag: BM121ORA0001062 Funded: (b) (4)  Delivery Location Code: FDA FDA US Food and Drug Administration 5600 Fishers Lane Rockville MD 20857 US Amount: (b) (4) Accounting Info: 2009-69999HR-252Z-730049OCPPO9SNT Appr. Yr.: 2009 CAN: 69999HR Object Class: 252Z CenterTag: 730049OCPPO9SNT Funded: (b) (4)				
2	Additional Funding for Coordinating Center Obligated Amount: (b) (4) Requisition No: 1063740  Delivery Location Code: WOC1 1401 ROCKVILLE PIKE 1401 ROCKVILLE PIKE ROCKVILLE MD 20852 US Accounting Info: Continued ...				(b) (4)

**CONTINUATION SHEET**

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NAME OF OFFEROR OR CONTRACTOR  
HARVARD PILGRIM HEALTH CARE INC 116298

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	2009-69999RC-252Z-S03401SIPS112GA Appr. Yr.: 2009 CAN: 69999RC Object Class: 252Z CenterTag: S03401SIPS112GA Funded:(b) (4)				
	The total amount of award: \$4,443,309.00. The obligation for this award is shown in box 20.				

## **Section B-SUPPLIES OR SERVICES AND PRICE/COSTS**

### **B.1 Type of Contract**

This is an Indefinite Delivery Indefinite Quantity contract. The period of performance shall commence from the period beginning contract award through twelve (12) months thereafter. There are four (4) Option Periods. Each Option Period, if exercised, shall be performed for a period of twelve (12) months.

At the discretion of the Contracting Officer, the Government may use a variety of contract types under the task orders to include: Firm Fixed Price (FFP), Labor Hour, or a combination thereof.

Each Request Task Order Proposal (RTOP) issued under this contract will identify the Government's determination of task order type.

### **B.2 Background**

In May 2008, the Secretary of Health and Human Services and the FDA Commissioner announced the Sentinel Initiative. The Sentinel Initiative is a long-term effort by the Agency to create a national electronic system for monitoring product safety. The Sentinel Initiative is intended to augment the Agency's existing post-market (primarily passive) safety surveillance systems and to allow the Agency to actively gather information about the post-market safety and performance of its regulated products.

As currently envisioned, the Sentinel Initiative will enable the Agency to capitalize on the capabilities of multiple, existing automated healthcare data systems (e.g. electronic health record systems, administrative claims databases, registries) to augment the Agency's current surveillance capabilities. The Sentinel Initiative will enable queries of disparate data sources quickly and securely for relevant product safety information. Data will continue to be managed by its owners, and only data of organizations who agree to participate in this system will be included. Questions would be sent to appropriate, participating data sources, who in turn would, in accordance with existing privacy and security safeguards, evaluate their data and send results for Agency review.

The Sentinel Initiative is a response to various calls for this type of effort from the Department of Health and Human Services (DHHS) and the Congress. In September 2005, the HHS Secretary asked the Agency to expand its current system for monitoring medical product performance and to explore the possibility of working with multiple automated healthcare data systems to augment the Agency's current capabilities of identifying and evaluating product safety information. The Secretary recommended that the Agency explore creating a public-private collaboration as a framework for such an effort, leveraging large, automated healthcare databases.

In 2006, the IOM issued a report, entitled *The Future of Drug Safety—Promoting and Protecting the Health of the Public*.<sup>1</sup> Among other suggestions, this IOM report recommended the Agency identify ways to access other health-related databases and create a public-private partnership to support safety studies.

In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007<sup>2</sup> (FDAAA). Section 905 of this statute calls for the HHS Secretary to develop methods to obtain access to disparate data sources and to establish an active post-market risk identification and analysis system that links and analyzes safety data from multiple sources. The law sets a goal of access to data from 25 million patients by July 1, 2010, and 100 million patients by July 1, 2012. The law also requires the Agency to work closely with partners from public, academic, and private entities. The Agency views its Sentinel Initiative as a mechanism through which some of the requirements mandated in this legislation can be carried out.

The Sentinel Initiative is a long-term effort that must proceed in stages. The initial stage of the Sentinel Initiative has allowed the Agency to further refine the requirements and develop the scope. The Agency has funded 8 contracts to support this initial stage.<sup>3</sup> In addition to this ongoing contractual work, there are many ongoing activities in the public and private sector that will inform the Sentinel Initiative. The Agency has hosted a series of meetings with various stakeholder groups, to include other federal agencies; data sources and environments; academics and experts; patient, consumer, and provider groups; and IT vendors. In addition, in December 2008 a public workshop was held to discuss the Sentinel Initiative with the following objectives:

- To provide an update on the current status of the Sentinel Initiative and allow for comment from all stakeholders
- To discuss potential governance models and their implications
- To discuss approaches to ensuring continued involvement of all stakeholders as the initiative evolves

The objective of this contract is not to create the Sentinel System, but to provide the

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<sup>1</sup> Institute of Medicine, *The Future of Drug Safety—Promoting and Protecting the Health of the Public*, September 22, 2006, <http://www.iom.edu/>.

<sup>2</sup> Food and Drug Administration Amendments Act of 2007, Public Law 110-85, was signed into law in September 2007. See Title IX, Section 905.

<sup>3</sup> Evaluating Potential Sentinel Network Data Sources for Blood and Tissue Product Safety Surveillance and Studies, Evaluation of Potential Data Sources for a National Network of Orthopedic Device Implant Registries, Evaluation of Timeliness of Medical Product Uptake for Surveillance in Health Care Databases for the Sentinel Initiative, Evaluation of Existing Methods for Safety Signal Identification for the Sentinel Initiative, Defining and Evaluating Possible Database Models to Implement the Sentinel Initiative, Evaluation of Potential Data Sources for the Sentinel Initiative, Developing a Governance and Operations Structure for the Sentinel Initiative, and Engagement of Patients, Consumers, and Healthcare Professionals in the Sentinel Initiative.

## Efforts to Develop the Sentinel Initiative

necessary support to facilitate the development of the Sentinel Initiative and carry out mandates delineated in FDAAA, including, but not limited to, requirements in Section 905. This will be carried out via the development of specific tasks, as deemed necessary by the Agency, and outlined below in the Scope of Work.

The work carried out on individual tasks will provide specific deliverables. These would be integrated with what has been learned from ongoing contractual work, as well as with other ongoing activities in both the public and private sectors. These cumulative efforts will aid in further understanding the feasibility and utility of these data and methodologies, primarily for active medical product surveillance.

The FDA would seek to undertake new activities to develop the scientific operations needed for the Sentinel Initiative. Specifically, FDA aims to fund a single coordinating center with continuous access to automated healthcare data systems, which would have the following capabilities:

- Provide a "laboratory" for developing and evaluating scientific methodologies that might later be used in a fully-operational Sentinel Initiative.
- Offer the Agency the opportunity to evaluate safety issues in existing automated healthcare data system(s) and to learn more about some of the barriers and challenges, both internal and external.

**The contractor may be excluded for future work on the Sentinel Initiative described in paragraph B.2, Background.**

### **B.3 Placement of Task Orders**

When contractual services, associated materials are required under this contract to perform, the Government will issue a task order. The Contracting Officer (CO) will provide a written task order request document to the Contractor describing the task project. The Request Task Order Proposal against this contract will be placed in writing, by means of a written task order. The Contracting Officer or his/her designee is/are the only person(s) authorized to place orders.

Task Orders will be either firm fixed price or labor hours.

A. Authorized Ordering Activities: The Contracting Officer of the FDA may place orders under this contract. Except as may be otherwise specifically stated therein, whenever the words, "Contracting Officer" are used in the schedule of this contract, they shall be deemed to mean the Contracting Officer of the ordering activity, or which the Contracting Officer has full responsibility for administering all contractual actions arising from any task order issued by the ordering activity.

The Contracting Officer, or his/her representative, whose signature appears on this contract, has the sole responsibility and authority to make any changes to the provisions of this contract.

B. Content of Order: Each task order placed under this contract shall include the following information:

1. The contract number, task order number, and date of order.
2. Applicable accounting and appropriation data, and special invoicing instructions where applicable.

Additional information can include:

1. Item number and description, quantity and unit price.
2. Cost and hours (as negotiated), extended amounts, fee (if applicable), total estimated.
3. Delivery or performance date.
4. Place of delivery or performance (including consignee).
5. Packaging, packing, and shipping instructions, if any.
6. Such other terms and conditions as may be pertinent and peculiar to the particular tasks thereby ordered.
7. Individual orders will reflect the requirement of particular circumstances as applicable. Urgent orders will cite peculiar terms and requirements.

C. Processing of Orders by the Contractor: The Task Order Proposal and all supporting information shall be delivered to the Government not later than ten (10) calendar days after the Government issues the initial Task Order Request.

#### **B.4 Minimum and Maximum Ordering Amounts**

The contract minimum amount will be satisfied with award of the base contract and the contract maximum amount will be (b) (4) over five (5) years per FAR 16.504(a)(4).

#### **B.5 Prices/Costs**

The Contractor shall propose fully loaded fixed hourly rates for services expected to be required to meet all current and future requirements under this contract. These rates shall apply to all task orders awarded under this contract. Labor categories and skill levels shall reflect a broad range of technical and business disciplines and experience levels that may be needed to support both small and large developmental efforts. The labor category rates specified shall be fixed hourly rates which include, as a minimum, the following: wages, indirect costs (including overhead, local taxes, fringe benefits and general and administrative expenses), and profit.

#### **B.6 Travel Policy**



**Efforts to Develop the Sentinel Initiative**

The Government will reimburse the Contractor for the allowable travel costs incurred by the Contractor in performance of the contract and determined to be in accordance with FAR Part 15, subject to the following provisions:

**GENERAL.** Travel required for tasks assigned under this contract shall be governed in accordance with rules set forth for temporary duty travel in the Federal Travel Regulations and the Standardized Regulations (Government Civilians, Foreign Areas). The Federal Travel Regulations are available on a subscription basis from the Superintendent of Documents, U.S. Government Pricing Office, Washington, DC. 20402, Stock No. 022-001-81003-7. The Standardized Regulations (Government Civilians, Foreign Areas), Section 925 is available on a subscription basis from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC. 20403, Stock No. 744-008-00000-0. All Contractor travel shall be submitted in writing for review to the COTR and approved in advance by the Contracting Officer.

**TRAVEL.** Travel, subsistence, and associated labor charges for travel time are authorized for travel beyond a 50-mile radius of the Local Office or official duty station, whenever a task assignment requires work to be accomplished at a temporary alternate location. The Government will not reimburse the Contractor for any travel within a 50-mile radius of the Contractor's Local Office or official duty station.

**PER DIEM.** Per diem for travel on tasks assigned under this contract will be reimbursed at a rate not to exceed the amount authorized in the Federal Travel Regulations and the Standardized Regulations (Government Civilians, Foreign Areas).

**LODGING.** Lodging will be reimbursed up to the limits established in the Government travel regulations for Federal Government personnel.

**MEALS AND INCIDENTALS.** Meals and Incidentals (M&IE) shall be reimbursed at the applicable rate allowable established by the Government regulations and published in the Per Diem Supplement 925 to the Standardized Regulations.

**AUTOMOBILES.** For travel where use of personal automobile has been specifically authorized, mileage reimbursement shall be computed on the basis of miles traveled from starting point to destination per the current Rand McNally Mileage Guide. Other actual related miscellaneous expenses, such as toll and parking fees, accrued in conducting business associated with tasks assigned under this contract, will be reimbursed. Car rentals require advance COTR approval in writing except under unusual circumstances and will be authorized only when consistent with good business practice and generally at a cost not to exceed actual cost of renting compact automobile (one for maximum of five (5) Contractor personnel), unless extenuating circumstances (e.g., excess baggage) requires other arrangements.

**TRAVEL ARRANGEMENTS.** The Contractor is responsible for making all travel arrangements during the conduct of tasks assigned under this contract. All air travel shall

**Average (of the high and low rates) labor category costs for OFF-SITE LOADED PRICE TABLE**  
**\*\*\*NOTE average costs are derived from the average of each of the 25 collaborating institutions labor rates**  
**Key Personnel per RFP Instructions are BOLDDED (P) = Richard Platt)**

	Average Hourly Rate	Average Hourly Rate	Average Hourly Rate	Average Hourly Rate	Average Hourly Rate	Average Hourly Rate	Average Hourly Rate
0001 - I	Principal Investigator	\$323.65	\$338.60	\$443.23	\$350.06	\$465.39	\$364.07
0001 - II	Co-Investigator I	\$422.13	\$435.72	\$208.92	\$216.58	\$216.58	\$224.54
0001 - III	Co-Investigator II	\$201.54	\$172.81	\$181.45	\$159.00	\$159.00	\$168.68
0001 - IV	Co-Investigator III	\$164.58	\$153.32	\$148.12	\$148.40	\$148.40	\$158.53
0001 - V	Co-Investigator IV	\$148.12	\$148.40	\$148.40	\$148.40	\$148.40	\$148.40
0001 - VI	Co-Investigator V	\$143.37	\$129.12	\$129.12	\$129.12	\$129.12	\$129.12
0002 - I	Program Manager	\$122.97	\$107.19	\$107.19	\$111.38	\$111.38	\$115.73
0002 - II	Program Manager II	\$103.18					
0004	Senior Research Analyst	\$138.83	\$144.92	\$84.21	\$151.12	\$157.92	\$164.84
0005	Research Analyst	\$81.54	\$84.21	\$84.21	\$86.97	\$89.92	\$92.76
0013	Quality Assurance Specialist	\$105.61	\$100.41	\$100.41	\$114.78	\$119.72	\$124.73
0013 - I	Quality Assurance Specialist I	\$75.09	\$78.19	\$81.58	\$84.51	\$87.59	\$89.74
0013 - II	Quality Assurance Specialist II	\$70.64	\$73.59	\$76.69	\$79.39	\$82.19	\$84.51
0015	Database Manager	\$162.50	\$169.50	\$169.50	\$176.50	\$184.31	\$192.12
0015 - I	Database Manager I	\$78.70	\$82.13	\$82.13	\$85.71	\$89.44	\$93.34
0012	Consultant Physician	\$437.19	\$455.72	\$475.04	\$495.64	\$516.54	\$537.84
0012 - II	Consultant Physician II	\$198.26	\$204.46	\$210.85	\$217.45	\$224.25	\$231.25
0006	Principal Epidemiologist	\$628.14	\$659.54	\$692.52	\$727.15	\$763.50	\$799.79
0007	Senior Epidemiologist	\$227.25	\$238.61	\$250.54	\$263.07	\$276.22	\$289.54
0008	Junior Epidemiologist	\$121.15	\$125.15	\$129.28	\$133.54	\$137.96	\$142.54
0008 - II	Junior Epidemiologist II	\$94.31	\$97.50	\$91.06	\$93.79	\$96.50	\$99.24
0008 - III	Junior Epidemiologist III	\$50.83	\$52.75	\$54.90	\$56.55	\$58.24	\$60.00
0011	Senior Statistician	\$126.54	\$132.87	\$139.51	\$146.49	\$153.81	\$161.33
0011 - II	Senior Statistician - II	\$147.12	\$152.56	\$158.23	\$164.12	\$170.24	\$176.54
0011 - III	Senior Statistician - III	\$82.89	\$85.74	\$88.61	\$91.55	\$94.79	\$98.15
0016	Survey Scientist	\$195.22	\$202.85	\$210.52	\$218.73	\$227.48	\$236.79
0016 - II	Survey Scientist II	\$98.43	\$101.59	\$104.67	\$107.93	\$111.30	\$114.84
0014	Nurse Abstractor	\$121.63	\$126.86	\$132.15	\$138.01	\$143.93	\$149.98
0014 - II	Nurse Abstractor II	\$53.20	\$55.29	\$57.46	\$59.73	\$62.08	\$64.54
0009	Coding Specialist	\$45.38	\$46.86	\$48.39	\$49.98	\$51.61	\$53.28
0003	Project Manager	\$132.89	\$139.53	\$146.51	\$153.84	\$161.33	\$168.98
0003 - II	Project Manager II	\$83.45	\$86.60	\$89.87	\$93.27	\$96.81	\$100.47
0003 - III	Project Manager III	\$71.70	\$75.28	\$79.04	\$83.00	\$87.15	\$91.54
0010	Research Assistant	\$57.24	\$60.32	\$63.36	\$66.51	\$69.79	\$73.19
0010 - II	Research Assistant II	\$46.96	\$48.59	\$50.38	\$52.22	\$54.14	\$56.14
0017	Materials Data Source Fees	\$36,000	\$35,000	\$35,000	\$35,000	\$35,000	\$35,000
0018	Chart Abstraction Fees	\$25	\$25	\$25	\$25	\$25	\$25

be on Commercial Airlines Coach Class. The Contractor shall not charge for direct labor hours during travel.

## **SECTION C-STATEMENT OF WORK/SPECIFICATIONS**

### **C.1 Scope of Work**

- a. The Contractor shall furnish the required personnel, materials, services, facilities, and otherwise do all things, required for or incident to the performance of the work as described below. The Contractor shall be prepared to develop a response to individual tasks as they are assigned.
- b. With the award of the base contract, the Contractor shall establish and maintain a single Coordinating Center that enables medical product surveillance using a distributed data model. The responsibilities of the Coordinating Center are to establish and maintain:
  1. A consortium of at least three automated healthcare data environments with varied data attributes (described below in C.1.b.1.b) to conduct analyses and other tasks ordered under task orders.
    - a. The Contractor shall provide technical expertise in pharmacoepidemiology and biostatistics for identifying, developing, validating, enhancing, and implementing advanced analytical and statistical methods (related to signal detection, signal strengthening, and signal validation) to address the specific issues, challenges, and objectives outlined for each task.
      - i. This would require demonstrated expertise in implementing standardized data elements in disparate automated healthcare data systems.
      - ii. Individual task orders may include testing data model options and/or characteristics to evaluate the effects on signal detection, signal strengthening, and signal validation.
    - b. Individual task orders will require the Contractor to access and utilize data from disparate automated healthcare data systems, including, but not limited to electronic health record systems, administrative claims databases, and patient registries, primarily for active medical product surveillance. It is preferred, but not required, that the Contractor be a holder of such an automated healthcare data system. The Contractor will need to demonstrate experience with methods for detecting, evaluating, and validating signals in these data. Additionally, they will have established working agreements

## Efforts to Develop the Sentinel Initiative

with other holders of automated healthcare data, and with the researchers that are intimately familiar with those data, whether or not they have been used for active medical product-surveillance before.

1. The Contractor shall have continuous access to various regularly updated automated healthcare data sources containing patient-level health encounter data from the United States in a platform that protects the integrity of patient records. The data sources shall each be a computerized system able to link each patient to all relevant medical care data including enrollment status, medical product exposure data, and coded medical procedures and outcomes. The data sources shall include, to the extent possible, a broad range of patient populations with regard to demographics and socioeconomic status. Linkage of this data source to additional information, including vital records, chronic disease and/or cancer registries, birth defect registries, and medical device registries, if available is also desirable.
2. The Contractor will only have direct access to any data owned by that organization. The Contractor will not create a repository for data from other data holders. Other data holders' data will remain behind their firewalls. Only summary results would be transmitted from the data holders to the Coordinating Center established under this contract.
3. The data sources shall have patient-level data describing health encounters and medical product use by individuals over time. The data sources shall have longitudinal data that shall be capable of following uniquely identifiable individuals over time.
4. Demographic information (e.g. age and gender), health history, diagnoses and procedures, and hospitalizations shall be available. Information on race/ethnicity shall be included where available, accompanied by documentation of the origin of this information.
5. For each patient these data shall contain prescription drug and biologic utilization information, typically including but not limited to the generic and brand name of the product, manufacturer, strength, dosage form, days supply, all dates dispensed, initial/continuing therapy indicator, quantity dispensed, instructions for use, indication for use and

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prescriber specialty. The data sources shall employ the use of a generally accepted, granular coding system for drugs and medical products, as well as for diagnoses and procedures. Furthermore, the Contractor shall have the ability to determine that the product was dispensed to the patient, rather than just prescribed to the patient.

6. Information on blood and tissue product use, including whole blood, plasma, red blood cells, platelets, and other transfused blood components, shall also be available. Plasma-derived products include polyclonal antibodies, immune globulin, antihemophilic clotting factors, albumin, other components extracted from human or animal plasma, and recombinant plasma-derived products. Examples of related biological products include, but are not limited to the following: hemin, thrombin, fibrin sealants, alpha-1 protease inhibitors, antivenins, Antithrombin III, digoxin immune FAB, and Protein C.
7. Optimally, medical device utilization by patients will also be captured, either at the device type level (e.g., by using diagnostic or procedural coding) or manufacturer level (e.g., by using registry data or bar code data).
8. Although accessible databases will often not have this information, it optimally will be useful to also capture specific product identification data in addition to brand and generic name, including: lot number (and model designation for devices); product integrity (e.g. visible damage to product or container closure); expiration date; whether a sterile product; and, whether a new molecular entity. To evaluate potential interactions, data shall be additionally captured when available on over the counter medications, dietary supplements and special diets.
9. All patient medical diagnostic information shall be represented in the data sources, including diagnoses and procedures associated with all ambulatory, emergency, chronic or acute care setting visits and their dates, diagnoses and procedures associated with related hospitalizations and their dates, and laboratory tests and results (if available) and their dates. Other health measures (such as family health history, height, weight, body mass index, smoking status, alcohol use, vital sign measurements, etc.), are of interest if available, as are results of imaging studies.

10. The Contractor shall have the capability of accessing medical records for validating coded diagnostic data used in analyses conducted under task order award. Patient identifiers will stay behind the firewalls of each data holder, and only aggregate information will be shared with the Coordinating Center and the Agency.
  11. The Contractor shall be responsible for ensuring that the uses of the data are compliant with HIPAA and any applicable state and local laws. The Agency will require no patient-, provider-, or health plan-specific identifiers, and any aggregated results provided to the Agency will be provided in a standard format. All activities performed by the Contractor shall and must comply with standards for privacy of individually identifiable health information and protect the rights of human subjects. All analysis of data shall be performed by the data holders in their secure environment without transfer of patient level data. If FDA deems it necessary to review certain data to protect the public, data holders shall make those data available in compliance with HIPAA for FDA review.
  12. All data accessed will be available as close to real-time as possible, so as to be conducive to surveillance.
  13. All data accessed will be from privately held, non-federal data sources from US patients. (FDA has access to Federal data sources through other means, so establishing relationships with Federal data holders is out of the scope of work of this effort).
2. A Planning Board, including representatives from the participating data environments (described above in C.1.b.1) and the FDA, to develop documents that specify the governance structure of the consortium that will enable the conduct of the proposed medical product safety evaluations.
  3. Under the Planning Board, a Safety Science committee charged with the day-to-day execution of analysis and evaluation for medical product safety.
  4. A means to allow for secure communication among the consortium of participating data environments to enable coordination of specific active medical product surveillance queries.
  5. Collaborations with FDA to identify, prioritize, and evaluate potential medical product-event pairs for medical product safety.

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- a. This would require the Contractor to have and maintain the ability to do the following, as outlined in the task orders, throughout the duration of the contract:
    1. Identify queries that will be appropriate to answer important questions related to a given topic;
    2. Form groups (i.e., cohorts) of patients exposed to one or more medical product and to follow them for the occurrence of one or more medical outcomes;
    3. Derive measures of therapeutic use, prescription drug consumption, exposure, and utilization using automated healthcare data systems and epidemiologic techniques;
    4. Access and use drug information resources and compendia;
    5. Develop algorithms for identifying possible adverse drug events using standard coding systems including but not limited to the International Classification of Diseases (ICD-9-CM) and clinical procedure coding (e.g., CPT codes).
    6. Provide a description of the processes used for quality assurance and quality control of all automated healthcare data systems and analyses used for projects with the Agency.
  - b. This would involve developing surveillance plans and study designs and developing and applying pharmacoepidemiological and biostatistical principles and methods.
  - c. Individual task orders may include developing, applying and/or evaluating advanced statistical approaches to safety signal detection, signal strengthening, and signal validation in automated healthcare data sources for regulated medical products during the postmarketing period.
  - d. Individual task orders may include training, as appropriate, on methods and tools employed in carrying out identified tasks. The type of training will be determined by the tools or methods developed, but could include development of training manuals, conduct of training sessions, or other methods deemed appropriate.
6. Processes that allow for use of the data that are compliant with HIPAA and any applicable state and local laws.

## **SECTION D –PACKAGING AND MARKING**

### **D.1 Packaging and Marking**

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. As appropriate, note on the face page of the report and when feasible on the binding: (1) “one volume only” or (2) “volume 1 of 2.



## **SECTION E-INSPECTION AND ACCEPTANCE**

### **E.1 Inspection and Acceptance**

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. The Contracting Officer's Technical Representative is the duly authorized representative of the Contracting Officer and is responsible for inspection and acceptance of all items to be delivered under this contract.
- c. Inspection and acceptance of the Contractor's performance shall be in accordance with the applicable FAR clauses in item d. below.
- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

52.246-4	Inspection of Services-Fixed Price	AUG 1996
52.246-6	Inspection-Time and Material and Labor Hour	MAY 2001

## SECTION F-DELIVERIES OR PERFORMANCE

### F.1 Reports/Deliverables

These requirements will vary by task and are to be determined upon issuance of individual task orders.

These may include:

- Weekly status/progress report via email to include work completed, work planned, issues to be addressed, project risks, level of effort/hour utilization and project decisions. Additionally, briefing materials (presentations) for FDA personnel in the form of PowerPoint slides or Microsoft Word white papers to articulate further detail about deliverables
- Teleconference to step through the weekly status/progress report with COTR and key stakeholders

All deliverables as defined by this Statement of Work shall be provided to the COTR in draft electronic form for comment before a final version is prepared in response to FDA comments. The COTR shall have 5 business days to review and comment on each final deliverable (excludes weekly status/progress report). The Contractor shall implement necessary changes within 5 business days of the change notification, unless otherwise by the COTR in writing

The Contractor shall be familiar with Section 508 requirements as described at <http://www.section508.gov/> in order to ensure that software and documents generated as part of the tasks are fully Section 508-accessible. Applicable sections include:

(As referenced in Summary of Section 508 Standards on Section 508 website)

#### Computer Applications

##### ***Technical Standards (Subpart B)***

- Software Applications and Operating Systems (1194.21)
- Web-based Intranet and Internet Information and Applications (1194.22)
- Video or Multimedia Products (1194.25)

- Presentations and training materials

Reports, Presentations and Training materials

***Information, Documentation, and Support (Subpart D)***

**F.2 Delivery Instructions for Reports**

Department of Health and Human Services  
Food and Drug Administration  
5600 Fishers Lane, Room 14B-45  
Rockville, MD 20857  
Attn: Melissa Robb  
[Melissa.Robb@fda.hhs.gov](mailto:Melissa.Robb@fda.hhs.gov)

**F.3 Period of Performance**

The period of performance shall be from:

Base Year September 23, 2009 through September 22, 2010  
Option Year One (1) September 23, 2010 through September 22, 2011  
Option Year Two (2) September 23, 2011 through September 22, 2012  
Option Year Three (3) September 23, 2012 through September 22, 2013  
Option Year Four (4) September 23, 2013 through September 22, 2014

**F.4 CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEB 1998)**

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.acquisition.gov/comp/far/index.html>.

**FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:**

52.242-15	Stop Work Order	AUG 1989
52.242-17	Government Delay of Work	APR 1984
52.249-14	Excusable Delays.	APR 1984

## SECTION G- CONTRACT ADMINISTRATION DATA

### G.1 Contracting Officer Technical Representative

- A. The COTR responsible for the technical requirements covered by this contract, as contemplated by Clause G-2, "Technical Monitoring" hereof, will be designated by separate correspondence. An alternate COTR will also be designated by separate correspondence.
- B. The COTR may be changed at any time by the Government without prior notice to the Contractor but notification of the change, including the name and address of the successor COTR, will be promptly provided to the Contractor by the Contracting Officer in writing.

The following COTR will represent the Government for the purpose of this contract:

Department of Health and Human Services  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857  
Attn: Melissa Robb  
[Melissa.robbs@fda.hhs.gov](mailto:Melissa.robbs@fda.hhs.gov)  
(301) 827-9691

The COTR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance. The Government may unilaterally change its COTR designation.

### G.2 Technical Monitoring

- A. Performance of the work under this contract shall be subject to the technical monitoring of the COTR. The term "technical monitoring" is defined to include the following:
  - 1. Technical directions to the Contractor which shift work emphasis between work areas or tasks, require pursuit of certain lines of inquiry, fill in details or otherwise serve to accomplish the contractual scope of work;
  - 2. Providing information to the Contractor for assistance in the interpretation of drawings, specification or technical portions of the work description; and

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3. Review and, where required by the contract, approval of technical reports, drawings, specifications and technical information to be delivered by the Contractor to the Government under the contract.
  - B. Technical direction must be within the general scope of work stated in the contract. The COTR does not have the authority to and may not issue any technical direction which (i) constitutes an assignment of additional work outside the general scope of the contract, (ii) constitutes a change as defined in the contract clause entitled "Changes," (iii) in any manner causes an increase or decrease in the total estimated contract cost, the fixed fee, or the time required for the contract performance, or (iv) changes any of the expressed terms, conditions, or specifications of the contract.
  - C. All technical directions shall be issued in writing by the COTR or shall be confirmed by him/her in writing within five (5) working days after issuance.
  - D. The Contractor shall proceed promptly with the performance of technical directions duly issued by the COTR in the manner prescribed by this article and within his/her authority under the provisions of this article.
  - E. If, in the opinion of the Contractor, any instruction or direction issued by the COTR is within one of the categories as defined in B. (i.) through B. (iv.) above, the Contractor shall not proceed but shall notify the Contracting Officer in writing within five (5) working days after the receipt of any such instruction or direction and shall request the Contracting Officer to modify the contract accordingly. Upon receiving such notification from the Contractor, the Contracting Officer shall issue an appropriate contract modification or advise the Contractor in writing that, in his/her opinion, the technical directions are within the scope of this provision and does not constitute a change under the "Changes" clause of this contract. The Contractor shall thereupon proceed immediately with the direction given.

Any failure of the parties to agree upon the nature of the instruction or direction or upon the contract action to be taken with respect thereto, shall be subject to the provisions of the contract clause entitled "Disputes."

### **G.3 Contracting Officer**

- (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 and the individual task orders.
- (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.

### **G.3.1 Contracting Officer Information**

Department of Health and Human Services  
Food & Drug Administration, OAGS  
Attention: Doreen Williams, Room 2099  
5630 Fishers Lane  
Rockville, MD 20857  
Phone: (301) 827-3366  
Email: Doreen.Williams@fda.hhs.gov

### **G.3.2 Administrating Contract Specialist Information**

Department of Health and Human Services  
Food & Drug Administration, OAGS  
Attention: Tara Hobson, Room 2142  
5630 Fishers Lane  
Rockville, MD 20857  
Phone: (301) 827-9691  
Email: Tara.Hobson@fda.hhs.gov

### **G.4 Key Personnel**

The Contractor shall provide the names and qualifications of the key personnel assigned to this contract. The individuals cited below are key personnel.

<u>Name</u>	<u>Title</u>
Program Manager	K. Lane
Principal Investigator	Richard Platt
Principal Epidemiologist	See individual task orders
Senior Epidemiologist	See individual task orders
Senior Statistician	See individual task orders

In the event that any of the personnel listed as key personnel are unable to perform because of health, resignation from the Contractor's employ, or any other reasons, the Contractor shall promptly submit to the Contract Specialist, a detailed written explanation of the situation, the proposed substitution, complete resumes for the proposed substitute, and any other information necessary for the approval of the substitution. No substitutions shall be made without prior written approval of the Contract Specialist. No increase in contract pricing will be allowed when substitutions are authorized by the government.

## **G.5 Invoice Submission**

Pursuant to the provisions of the following FAR Clauses: 52.232-25, Prompt Payment (OCT 2008); 52.232-33, Payment by Electronic Funds Transfer-Central Contractor Registration (OCT 2003); and 52.232-34, Payment by Electronic Funds Transfer-Other Than Central Contractor Registration (MAY 1999) in Part II, Section I, the Contractor shall submit vouchers or invoices, using a Standard Form 1034 and Standard Form 1035 or facsimile, for costs incurred and claimed for reimbursement in accordance with the following instructions.

A. In accordance with clause 52.232-33 or clause 52.232-34, all payments made under this contract shall be made using electronic funds transfer through the Automated Clearing House (ACH). The Contractor shall provide the following information to the Food and Drug Administration, Office of Financial Services, HFA-720, 12345 Parklawn Drive, Rockville, MD 20857:

1. Routing transit number of the financial institution receiving payment.
2. Number of account to which funds are to be deposited.
3. Type of depositor account ("C" for checking, "S" for savings).

B. An original and two (2) copies shall be submitted to the attention of the Administrating Contract Specialist at the following address:

Department of Health and Human Services  
Food & Drug Administration, OAGS  
Attention: Tara Hobson, Room 2142  
5630 Fishers Lane  
Rockville, MD 20857  
Phone: (301) 827-9691  
Email: Tara.Hobson@fda.hhs.gov

## **SECTION H-SPECIAL CONTRACT REQUIREMENTS**

### **H.1 Access to Non-Public Information**

All Contractor and subcontractor employees are required to sign the Contractor's Commitment to Protect Non-Public Information Agreement form provided as an attachment to this contract (Attachment 1). If a person who has signed this agreement resigns, is dismissed, or is otherwise no longer working on this contract, the Contractor shall notify the FDA Contracting Officer's Technical Representative (COTR) and Contracting Officer. Any new Contractor and subcontractor employees assigned to this contract shall sign the form, and the Contractor shall hand-deliver it (ten (10) days prior to commencement of work) to the Contracting Officer.

The prime Contractor, subcontractors, and consultants shall not be provided nor possess non-public information in any form unless written approval and a facility clearance have been granted.

#### **Briefings**

A FDA representative (typically, the COTR) will conduct an orientation briefing for the Contractor/Contractor employees. The briefing will stress: (1) the importance of protecting non-public information; (2) specified computer/ADP requirements as outlined in the DHHS Automated Information Systems Security Program Handbook; and (3) the consequences of unauthorized disclosure of non-public information. Briefing updates will be conducted annually.

The Contractor shall brief all Contractor employees, subcontractors and consultants regarding the sensitivity of the information to be handled under the contract and of the responsibility to protect it. The briefing shall stress that the information is non-public and shall not be disclosed to any unauthorized source. The Contractor shall conduct an updated briefing annually and shall submit a report to the FDA COTR within ten (10) days after the briefing which includes: an outline of the briefing, a copy of any briefing materials, date briefing was conducted and the names of the attendees.

If this is an automated data processing/telecommunications (ADP/TC) contract, in addition to the above briefings, the FDA COTR and the FDA Center/Office Information Systems Security Officer (ISSO) will brief Contractor and subcontractor personnel and consultants on security measures required pertinent to any hardware/software being utilized. Furthermore, appropriate Contractor and subcontractor personnel and consultants shall attend training courses as directed by the FDA to fulfill requirements of the Computer Security Act of 1987. These courses are generally one (1) day in length; and attendance at one (1) course is sufficient. This training will be provided at no cost to the Contractor.



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Provide briefings to the Agency on deliverables and findings, e.g., following proposed approaches to analysis, the findings of conducted analyses, and other tasks, to obtain agency input.

All task orders issued by the Agency under this contract shall require the following:

1. Confidential or otherwise privileged information disclosed by the Agency with Contractor shall not be used by the Contractor to solicit or in any other way encourage industry funding/financial sponsorship of projects to be performed by the Contractor. In the event that an outside party such as a drug sponsor independently requests that the Contractor conduct surveillance on a safety issue that the Agency has previously discussed with the Contractor but the Agency has not requested the Contractor to perform the surveillance on that issue, the Contractor may conduct such surveillance only if both of the following conditions are satisfied: (1) the Contractor shall not divulge confidential and privileged information previously disclosed by the Agency; and (2) the Contractor shall recuse itself from all subsequent conversations with the Agency about the safety of the involved drug product(s).
2. Each Contractor/subcontractor employee who may have access to non-public Department information under this task order shall complete the Commitment to Protect Non-Public Information - Contractor Agreement ([http://nitaac.nih.gov/downloads/ciosp2/Contractor\\_Employee\\_Non-Disclosure.doc](http://nitaac.nih.gov/downloads/ciosp2/Contractor_Employee_Non-Disclosure.doc)). A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the COTR prior to performing any work under the contract.
3. The Contractor shall keep confidential all communications with FDA, or with data holders, concerning queries and responses to queries, including the responses to the queries, unless authorized by the Agency in writing to make such information public. The Contractor shall guarantee strict confidentiality of the information/data that it is provided by the Government during the performance of the task order. The Government has determined that the information/data that the Contractor will be provided during the performance of the task order is of a sensitive nature. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.
4. This contract shall not constrain the Agency from releasing deliverables from these tasks prior to formal publication or presentation in a scientific forum. Under these circumstances, the Agency will work with the site collaborators to avoid jeopardizing publication of results.
5. The Contractor shall meet the obligations applicable to a "qualified entity" described in section 505(k)(4)(G) of the Federal Food, Drug, and Cosmetic Act, specifically:

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- **ENSURING PRIVACY.**—The Contractor shall ensure that it will not use data under the contract in a manner that—
  - a. violates the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;
  - b. violates sections 552 or 552a of title 5, United States Code, with regard to the privacy of individually-identifiable beneficiary health information; or
  - c. discloses individually identifiable health information when presenting drug safety signals and trends or when responding to inquiries regarding drug safety signals and trends.
  
- **COMPONENT OF ANOTHER ORGANIZATION.**—If the Contractor is a component of another organization—
  - a. the Contractor shall establish appropriate security measures to maintain the confidentiality and privacy of such data; and
  - b. the Contractor shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

**FEDERAL HEALTH ARCHITECTURE (FHA) HEALTH INFORMATION TECHNOLOGY REQUIREMENTS****INTEROPERABILITY**

Executive Order 13410:

Promoting Quality and Efficient Health Care in Federal Government

Administered or Sponsored Health Care Programs promotes efficient delivery of quality health care through the use of health information technology, transparency regarding health care quality and price, and incentives to promote the widespread adoption of health information technology and quality of care. To support this mission, the awardee shall, at a minimum, implement the following clause(s)/condition(s) and, in doing so, the actions and steps taken to implement the clause(s)/condition(s) shall not impose additional costs onto the Federal Government.

In Response to Executive Order 13410, the following clauses shall apply:

- Use recognized health information interoperability standards at the time of the system update, acquisition, or implementation, in all relevant information technology systems supported, in whole or in part, through this agreement/contract.

Where Offerors/awardees support or participate in health information [or data] exchange with disparate entities, offerors/awardees must be compatible with the following, where applicable architectures and data-exchange standards already exist:

- HHS Nationwide Health Information Network (NHIN)  
([www.hhs.gov/healthit/healthnetwork/background](http://www.hhs.gov/healthit/healthnetwork/background)).
- FDA Data Standards Council: Data Exchange Standards  
(<http://www.fda.gov/oc/datacouncil/>)
- HHS Data & Technical Standards: Health Information Technology Standards Panel (HITSP)  
(<http://www.hhs.gov/healthit/standards/activities/>)

## **H.2 Reporting Matters Involving Fraud, Waste and Abuse**

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in FDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is [\*\*Htips@os.dhhs.gov\*\*](mailto:Htips@os.dhhs.gov) and the mailing address is:

Office of Inspector General  
Department of Health and Human Services  
TIPS HOTLINE  
P.O. Box 23489  
Washington, D.C. 20026

## **H.3 Anti-Lobbying**

a. Contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or 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 legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the Contractor or any agent acting for the Contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

## **H.4 Organizational Conflicts of Interest**

As a regulatory agency charged with protection of the public health, the Food and Drug Administration (FDA) must maintain public confidence in the integrity of its decisions. The FDA has various policies and procedures that safeguard against both actual and

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apparent conflict of interest (COI) on the part of its employees. It is additionally critical that the FDA be assured that there is no actual or apparent COI on the part of either the Contractor's organization or its individual employees in performance of this contract action.

Contractors submitting proposals to perform work under this contract must assure the protection of the information and data they receive in performance or under this contract from unauthorized use or disclosure, and must avoid actions that will cause a reasonable person to question the impartiality of the Contractor, its employees, or the Government in the performance of this immediate contract and potential participation in future actions. Contractor will be held to the restrictions of the Organizational Conflict of Interest clause, unless an acceptable mitigation of risk plan is proposed, found acceptable by the Government and enforced.

**POTENTIAL CONFLICTS OF INTEREST SPECIFIC TO THIS CONTRACT -**

Contractors shall review the Statement of work included in each RTOP in detail to identify any particular aspects that may present organizational or individual COI, either actual or apparent.

**DEFINITION OF CONFLICT OF INTEREST -** Conflict of interest means that because of other activities or relationships with other persons or organizations, a person or organization is unable or potentially unable to render impartial assistance or advice to the Government, that the person's or organization's objectivity in performing the contract is or might be otherwise impaired, or that the person or organization has or might acquire an unfair competitive advantage (See FAR 9.501).

**SUBMITTAL OF CONFLICT OF INTEREST PLAN -** If it is determined that a COI exists, Contractors shall submit a COI Plan which outlines procedures to avoid, neutralize or mitigate COIs; whether actual or apparent, throughout the period of performance of the contract and the restriction period. The plan shall address step-by-step the checks and balances in place to detect potential or actual COI, organizationally and in connection with individual personnel, and shall describe the process of reporting COI to the FDA. It shall contain a statement of consent for FDA to inspect all records, correspondence and other documentation related to COI. If the COI Plan is deemed unacceptable by the FDA, further evaluation of the Contractor's proposal may not occur. Upon execution of the contract, the COI Plan shall be incorporated by reference into the contract.

The plan shall include elements of the following:

**A. CORPORATE STRUCTURE -** The plan shall describe any parent company relationship, and list all affiliates and subsidiaries whose work may present a COI. In addition, the plan shall be updated as soon as there are any changes that may affect work performed under this contract.

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Contractors must describe all relevant information concerning any past, present or planned interests that may have a bearing on whether they (including their chief executives and directors, or any proposed consultant or subcontractor) have an organizational conflict of interest in regard to the responsibilities described in the Statement of Work.

**B. INDIVIDUAL EMPLOYEE COI/NONDISCLOSURE AGREEMENTS** - The COI Plan shall require that ALL employees (any Contractor or employee of a Contractor, including a Contractor, subcontractors, consultants) performing work under this contract, and/or any work related to this contract, execute a COI/Nondisclosure Agreement. In signing this agreement, the individual agrees to report to the proper authority within the Company, as identified by the Company, information that may affect a determination of individual COI, whether actual, apparent, or potential. This means that employees must disclose/identify all specific financial interests (e.g., stocks, stock options, bonds) and activities (e.g., other employment and consulting).

The COI/Nondisclosure Agreement must also contain a statement assuring FDA that the individuals who will be performing work under this contract have read and understand the company's COI plan and procedures. A list of those employees who have done so shall be retained by the company.

The COI/Nondisclosure Agreement shall include, but need not be limited to, the following:

- 1) An assurance that the employee has agreed to act impartially and not give preferential treatment to any individual or organization who has submitted applications, information and/or data to FDA.
- 2) An assurance that the employee has agreed not to solicit any gift or other item, nor accept any gift or other item, of monetary value exceeding \$20 from any person or entity seeking official action from, doing business with, or conducting activities related to the evaluations and work performed under this contract. Aggregate market value of individual gifts shall not exceed \$50.00 in a calendar year.
- 3) An assurance that the employee has agreed not to disclose to any unauthorized person any information and/or data within his or her purview, or to which he/she has access as a result of performing work under this contract.
- 4) An assurance that the employee has agreed not to engage in financial transactions using nonpublic information or allow the improper use of such information to further any private interest.
- 5) An assurance that the employee has agreed not to participate in any matter involving specific parties who are likely to or can directly affect the employee's own financial interest or the financial interests of a member of his household or a relative with whom they have a close personal relationship.

6) Employees shall disqualify themselves from participating in particular matters involving former employers, or their representatives, and from whom they have worked within the past one (1) year.

FDA will, upon request, provide information to Contractors on the COI standards it applies to its personnel. These standards may be adopted in the COI Plan as one means of safeguarding against individual COI.

**C. ANNUAL SUBMISSION OF COI/NONDISCLOSURE AGREEMENTS** - The COI Plan shall describe the company process for submission of annual COI/Nondisclosure Agreements for both the organization and for individual employees (if performance of the immediate contract plus the restriction period extends beyond one year).

**D. NOTIFICATION** - The COI Plan shall clearly delineate who has the official responsibility for making COI determinations and clearances within the Contractor's organization. Generally, this is someone at a mid to upper level of management. This official shall be free of any personal conflict for the purpose of making COI determinations, (e.g., a program manager who received bonuses based on the total amount of sales may not be free of any conflicts).

Each employee shall be cleared by the Contractor as free of COI prior to performing under this contract. If the Contractor believes that a potential for conflict exists, the individual may not be assigned to, or perform under, this contract in any manner. If the Contractor has difficulty in determining whether a potential or actual conflict exists, the Contractor shall submit a written request for resolution of the issue within 14 days to the Contracting Officer.

The Contractor agrees to make available to the FDA, on demand, all disclosures of employment and financial interests for all individual employees performing work under this contract.

**E. CORRECTIVE ACTION** - The plan shall clearly identify the process that is required when notifying the FDA of any actual, apparent, or potential organizational or individual COI, and the action that the company has taken or will take to avoid, neutralize, or mitigate the COI. The plan shall describe corrective actions, which may include any actions necessary to remedy or prevent a potential infringement of COI by the employee or the organization, including but not limited to restitution, change of assignment, disqualification, divestiture, or termination of an activity.

**F. TRAINING** - The COI Plan shall describe how all employees are trained in the basics of COI. An employee shall receive COI training as soon as possible after being assigned to work on the FDA contract. Thereafter, employees shall receive COI awareness training (annual, if performance of the immediate contract plus the restriction period extends beyond one year) that shall include, at a minimum, a review of the nondisclosure agreement language and any changes to the company's COI Plan. In addition, the

company's COI Plan shall be available for all employees to review. The Contractor is encouraged to routinely disseminate all current COI information to its employees.

#### **H.5 Clearance for Publication**

No information furnished to or generated by the contractor in the performance of this contract shall be released to the public until it has been reviewed by the COTR for accuracy of factual data and interpretation. The Government shall have **30** calendar days after receipt of the manuscript or other written draft of the material to be released, to review, comment, and return to the contractor.

#### **H.6 Accountability and Security**

All Contractor and Subcontractor employees who will have access to Government information and/or sensitive materials must sign a Confidentiality Agreement. It is the responsibility of the Contractor to assure that such Agreements have been signed before

access is permitted. Copies of signed agreements shall be provided to the Contracting Officer.

The following procedures and rules shall be followed by the Contractor according to the Privacy Act of 1974, as amended, and the FDA security and confidentiality procedures applicable to this contract:

- a) All information and reports generated from this project are, and will remain, the property of the FDA. No Government document or information, oral or written, either in final or draft form, will be provided to non-FDA sources by any Contractor personnel without the written approval of the Contracting Officer during this contract or at any later date.
- b) No data covered by privacy laws may leave the United States for any purpose or under *any* circumstances unless prior approval by the Contracting Officer is first obtained.
- c) The Contractor must ensure that all FDA data or documents processed or developed under this contract, and the information contained therein, are protected from unauthorized use and mishandling by assigned personnel.
- d) The Contractor shall not reveal, during the performance of this contract or later, any of the operating methods or systems, contents of files, names of persons, firms, or places mentioned under the contract that the Contractor may acquire, unless approved in writing by the Contracting Officer.
- e) Under the provisions of the Privacy Act of 1974, as amended, that is applicable to this contract, the Contractor and Contractor personnel may be subject to its criminal penalties. The Contractor agrees that, upon termination of the contract, whether with or without

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cause, the Contractor has no property or possessor right to any of the correspondence, files or materials, of whatever kind and description, or any copies or duplicates of such, whether developed/prepared by the Contractor or furnished to the Contractor by the technical office concerning the performance of this contract; and that, upon demand, the Contractor will surrender immediately to the Contracting Officer such items, matters, materials, and copies. A restraining order or an injunction may be issued against the Contractor for any violation of this provision, besides any other right or penalty by law that the Government may have.

### **H.7 Proprietary Rights – Government- Furnished Data and Materials**

The Government shall retain all rights and privileges, including those of patent and copy, to all Government-furnished data and materials. The Contractor shall neither retain nor reproduce for private or commercial use any data or other materials furnished under this contract. The Contractor agrees not to assert any rights at common law or in equity or establish any claim to statutory copyright in such data. These rights are not exclusive and are beyond any other rights and remedies to which the Government is otherwise entitled elsewhere in this contract.

### **H.8 Advanced Understanding**

Notwithstanding any of the above provisions, under certain circumstances, the Government may be required to share data or information it obtains under this contract with Congress, with a Federal court, or with another governmental body of competent jurisdiction. If it intends to share data or information obtained under this contract with Congress, with a Federal court, or with another governmental body of competent jurisdiction, the Government will take appropriate measures within its control in an effort to ensure that the information will be shared in a manner intended to protect the information from public disclosure.

Likewise, the Contractor must assure the protection of the information and data they receive under this contract from unauthorized use or disclosure, and must treat the information as confidential or otherwise privileged.

### **H.9 FDA 2119-1 Protection of Human Subjects, Research Involving Human Subject Committee (RIHSC) Approval of Research Protocols Required**

(a) All Offerors proposing research expected to involve Human Subjects shall comply with the regulations set forth in 45 CFR Part 46, and with the provisions at HHSAR 352.270-8(a), which are incorporated into this contract as FDA 2119. Upon initiation of a task order, the successful awardee shall discuss with the COTR which if any activities covered by the task order constitute research.

(b) The Offeror is required to have an acceptable Federal-Wide Assurance of Compliance on file with the Office for Human Research Protections (OHRP), 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, whenever it submits a proposal to



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the FDA for research that is expected to involve human subjects. Questions about Federal-Wide Assurances of Compliance shall be directed to OHRP. The Federal-Wide Assurance number shall be included in the Offeror's proposal. (OHRP doesn't send out letters of approval for FWAs)

(c) After the contract has been awarded, the Contractor shall take the following actions:

1. The Institutional Review Board (IRB) specified in the Offeror's Assurance of Compliance, hereafter referred to as "the local IRB," shall review the proposed research protocol. A letter from the local IRB stating that the proposed research protocol has been approved and adequately protects the rights and welfare of human subjects involved, or a letter stating that the proposed research is exempt under 45 CFR 46.101(b) shall be submitted to the Contracting Officer.

2. Upon award, the successful Offeror, hereafter "the Contractor," shall submit its proposed research protocol to the FDA's Research Involving Human Subjects Committee (RIHSC). The RIHSC will review the research protocol to assure that the rights and welfare of human subjects involved are adequately protected. The RIHSC will also determine whether the proposed research is exempt under 45 CFR 46.101(b). The Contractor shall submit a copy of the RIHSC's letter stating that it has reviewed and approved the proposed research protocol to the Contracting Officer of record.

(d) The Contractor shall not advertise for, recruit, or enroll human subjects, or otherwise commence any research involving human subjects until RIHSC has reviewed and approved its research. The Contractor may begin other limited aspects of contract performance prior to receiving RIHSC approval of the proposed research protocol. Research involving human subjects may commence immediately upon the Contractor's receipt of RIHSC approval; however the Contractor shall submit a copy of RIHSC's letter of approval to the Contracting Officer within three business days of its receipt.

(e) A Contractor's failure to obtain RIHSC approval of its proposed research will result in termination of its contract for default. However, failure to obtain RIHSC approval during RIHSC's initial review will not automatically result in termination of the contract. Instead, the Contractor may correct any deficiencies identified during the RIHSC review and resubmit the proposed research protocol to RIHSC for a second review. The Contractor is encouraged to solicit the RIHSC's input during the resubmission process.

(f) The Contractor shall seek RIHSC and local IRB review and approval whenever modifications, amendments or other changes are made to the research protocol. Such modifications, amendments and changes include, but are not limited to changes in investigators, informed consent forms, and recruitment advertisements. Changes may be instituted immediately after the Contractor has received both the local IRB and RIHSC approval; however, the Contractor shall submit a copy of the letter evidencing RIHSC's approval of the proposed changes to the Contracting Officer within three business days of

its receipt.

## **H.10 FDA 1335 Personnel Security Clearance Requirements**

### **1. BACKGROUND**

The Office of the Assistant Secretary for Management and Budget, Department of Health and Human Services (DHHS), requires that DHHS employees and contractor employees (including subcontractors) who will be working in a DHHS-owned or leased space and/or who will have access to DHHS equipment, and non-public privileged, proprietary, or trade secret information, undergo a background investigation of some type.

Contractor employees who will be in DHHS-owned or lease space for less than thirty (30) days are exempted from the background investigation requirement. These contractor employees must be escorted at all time while in DHHS-owned or leased space.

### **2. GENERAL**

The contractor shall submit the following items to the Contracting Officer, ten (10) calendar days prior to commencement of work under this contract:

- a. Certification that all required security form packets (See Charts A and/or B incorporated in this clause) and a list of contractor employees names for whom the requisite security information has been provided to Division of Security Operations, Policy and Planning, Personnel Security Staff.
- b. "Contractor's Commitment to Protect Non-public Information Agreement" forms signed by each employee named in paragraph a. above.

With the exception of costs associated with fingerprinting Contractor employees outside of the FDA Personnel Security Office, the Government will conduct all required background investigations at no cost to the contractor. The cost of fingerprinting Contractor employees at any location other than the FDA Personnel Security Office will be borne by the Contractor.

Contractor employees shall obtain security badges in order to access to DHHS-owned or leased property without an escort. (See Section 3 for details on the badging process). However, in the event that work must commence before security badges can be issued, contractor employees will be allowed onto DHHS-owned or leased property, but must be escorted at all times.

All Contractor employees who undergo a background investigation are required to log onto the Office of Personnel Management's (OPM's) Electronic Questionnaire for Investigation Processing (e-QIP) system to complete the forms necessary to initiate their background investigations. The forms required vary with the position risk levels for the contract.

The position risk levels for this contract are Non-Sensitive Positions - \_\_\_\_\_.

There are two (2) potential position risk levels, which are:

a. Non-Sensitive Positions (Level 1) (SEE CHART A) - Positions which involve the lowest degree of adverse impact on the efficiency of the Agency. The forms set forth by CHART A are required for Non-Sensitive Positions (Level 1). Contractor employees assigned to Level 1 who receive a security badge will be required to provide additional security information for a background investigation as specified in Paragraph 5 below.

b. Public Trust Positions (Levels 5 or 6) (SEE CHART B) - Positions in which the incumbent's actions or inaction could diminish public confidence in the integrity, efficiency, or effectiveness of assigned Government activities, whether or not actual damage occurs. The forms set forth by CHART B are required for Public Trust Positions (Levels 5 or 6). Contractor employees assigned Levels 5 or 6 must receive security badge as well as a background investigation.

In order to access the e-QIP system, Contractor employees must provide the appropriate Personnel Security Specialist with the following information: (a) full name; (b) position title; (c) social security number; (d) date of birth; (e) place of birth; (f) email address; and (g) phone number. The Personnel Security Specialist will use this information to initiate each Contractor employee into the e-QIP system. Once this is done, each Contractor employee will receive an email that contains a web link to access the e-QIP system, as well as instructions and additional forms needed to initiate the suitability background investigation. The COTR for the contract will provide the name of the appropriate Personnel Security Specialist to the Contractor.

A Contractor's failure to comply with the e-QIP processing guidelines will result in that Contractor's employees being denied access to FDA property until all security processing has been completed.

### 3. BADGING PROCESS

The FDA COTR will sponsor Contractor employees on the FDA Form 3391 for the purpose of obtaining an FDA Security Access Card. In order to obtain one, a contractor employee must receive a "favorable" fingerprint return. Fingerprints must be submitted to the Personnel Security Office at least ten (10) days prior to the commencement of work. Fingerprints will be submitted in one of two ways, depending on where the contract will be performed:

a. Contractor employees who will work in the Washington D.C. metro area will, at the direction of the FDA COTR or his/her designee, contact the Personnel Security Branch to schedule a fingerprinting appointment, or

b. Contractor employees who will work in a field office will submit fingerprints to:

Food and Drug Administration  
Personnel Security Staff, OSO  
5600 Fishers Lane  
PKLN 15A-22, HFA-640  
Rockville, MD 20857

Upon the receipt of a “favorable” fingerprint return, each Contractor employee must present two forms of identification in order to receive his or her badge. One form of identification must be a government-issued photo identification document. Acceptable forms of photo identification are referenced on the FDA Form 3391. Acceptable forms of secondary identification are listed on the back of the I-9 Form. This form can be obtained at <http://uscis.gov/graphics/formsfee/forms/files/i-9.pdf>

An individual who receives an unfavorable report may appeal that finding by submitting a written request to the Personnel Security Staff.

#### 4. BACKGROUND INVESTIGATIONS

The Government shall conduct an additional background investigation for those individuals named to risk Levels 1, 5 and 6 serving under this contract.

Required background investigations may include, but not be limited to:

- Review of prior Government/military personnel records;
- Review of FBI records and fingerprint files;
- Searches of credit bureaus;
- Personal interviews; and
- Written inquiries covering the subject's background.

Background investigations will be conducted by the Office of Personnel Management (OPM).

The Contractor is responsible for ensuring that the integrity of contract performance is maintained pending completion of all appropriate background investigations of contractor employees.

The Contractor shall submit the information required for eQIP access and other requisite forms for the risk level(s) specified. In addition, the contractor shall provide a cover letter which includes: the Contractor's name, the contract number, the name of the Contracting Officer administering the contract, the names of all Contractor employees' for whom a background check is required and those employees' social security numbers, dates of birth, and former names. This cover letter and all completed forms shall be transmitted, in a separate sealed envelope marked, "TO BE OPENED BY ADDRESSEE ONLY," to:

Food and Drug Administration  
OSO/Office of Security Operations  
Attn: Personnel Security Staff  
5600 Fishers Lane, PKLN 15A-22, HFA-640  
Rockville, MD 20857

The contractor shall send a separate letter to the Contracting Officer that includes the contract number and employee names.

The contractor shall advise its prospective employees that all standard forms submitted to the FDA will be forwarded to the Office of Personnel Management (OPM) for scheduling background investigations.

Personnel Security Staff will resolve with the contract employee any issues arising out of inaccurate or incomplete forms.

Employees who have been previously granted a Government security clearance shall advise Personnel Security Staff of the details of such clearances to determine if a previous clearance level is suitable for the current FDA position.

At any time, if a contractor employee for whom security forms have been submitted is terminated or otherwise ceases work under the contract, the contractor shall immediately notify Personnel Security Staff, in writing, with copies to the respective FDA COTR and Contracting Officer.

The OPM background investigation will take approximately 120 days. The Contracting Officer will notify the Contractor in writing if an employee is denied a clearance. Those individuals who have been cleared by Personnel Security Staff may continue to work under the contract. Those who are not cleared must cease work on the contract immediately.

If a Contractor employee changes job responsibilities under this contract, the contractor shall notify the Contracting Officer, and the Government will make a determination whether an additional security clearance is required.

In the event that a cleared individual is replaced, the contractor shall notify the Contracting Officer and comply with all requirements of this clause, as specified herein, prior to the commencement of work by the replacement individual.

The Contractor shall be responsible for the return of any Government issued security badges to the COTR.

## 6. NON-PUBLIC DATA PROTECTION

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The contractor shall protect the privacy of all information reported by or about contract employees and shall protect against unauthorized disclosure.

**H.11 Observance of Legal Holidays**

The Government hereby provides “notice” and the Contractor hereby acknowledges “receipt” that Government personnel observe the listed days as holidays:

Martin Luther King, Jr.’s Birthday	President’s Day
Memorial Day	Independence Day
Labor Day	Columbus Day
Veterans Day	Thanksgiving Day
Christmas Day	New Year’s Day

Any other day designated by Federal Statute  
 Any other day designated by Executive Order  
 Any other day designated by President’s Proclamation

When any such day falls on a Saturday, the preceding Friday is observed; when any such day falls on a Sunday, the following Monday is observed. It is understood and agreed between the Government and Contractor that observance of such days by Government personnel shall not “on its face” be cause for an additional period of performance, or entitlement of compensation except as set forth within the contract. Contractor employees performing duties for the Food and Drug Administration are not automatically relieved from duty by virtue of the fact that the Government employees are dismissed or given the day off.

**H.12 HHSAR 352.270–13 Tobacco-Free Facilities (January 2006)**

In accordance with Department of Health and Human Services (HHS) policy, the Contractor and its staff are prohibited from using tobacco products of any kind (e.g., cigarettes, cigars, pipes, and smokeless tobacco) while on any HHS property, including use in personal or company vehicles operated by Contractor employees while on an HHS property. This policy also applies to all subcontracts awarded under the contract or order. The term “HHS properties” includes all properties owned, controlled and/or leased by HHS when totally occupied by HHS, including all indoor and outdoor areas of such properties. Where HHS only partially occupies such properties, it includes all HHS-occupied interior space. Where HHS leases space in a multi-occupant building or complex, the tobacco-free HHS policy will apply to the maximum area permitted by law and compliance with the provisions of any current lease agreements. The Contractor shall

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ensure that each of its employees, and any subcontractor staff, is made aware of, understand, and comply with this policy.

## SECTION I-CONTRACT CLAUSES

### I.1 52.252-2 FAR 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): [www.arnet.gov](http://www.arnet.gov)

52.202-1	Definitions.	JUL 2004
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.	SEP 2006
52.203-7	Anti-Kickback Procedures.	JUL 1995
42.203-8	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.	SEP 2007
52.204-4	Printed or Copied Double-Sided on Recycled Paper.	AUG 2000
52.204-7	Central Contractor Registration	APR 2008
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment.	SEP 2006
52.215-2	Audit and Records - Negotiation.	MARCH 2009
52.215-8	Order of Precedence – Uniform Contract Format.	OCT 1997
52.215-17	Waiver of Facilities Capital Cost of Money.	OCT 1997
52.215-19	Notification of Ownership Changes.	OCT 1997
52.216-31	Time-and-Materials/Labor-Hour Proposal Requirements Commercial Item Acquisition	FEB 2007

If this contract is with an educational institution, the words "Subpart 31.3" are substituted for "Subpart 31.2" in Paragraph (a) of FAR Clause 52.216-7. If this contract is with a nonprofit organization other than an educational institution, the words "Subpart 31.7" are substituted for "Subpart 31.2" in Paragraph (a) of FAR Clause 52.216-7.

52.219-8	Utilization of Small Business Concerns.	MAY 2004
52.219-9	Small Business Subcontracting Plan ALT II	APR 2008
52.219-14	Limitations on Subcontracting.	DEC 1996
52.222-3	Convict Labor.	JUN 2003
52.222-21	Prohibition of Segregated Facilities.	FEB 1999
52.222-26	Equal Opportunity.	MAR 2007
52.222-35	Equal Opportunity for Special Disabled Veterans, Veterans	



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	of the Vietnam Era, and Other Eligible Veterans.	SEP 2006
52.222-36	Affirmative Action for Workers with Disabilities.	JUN 1998
52.222-37	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era.	SEP 2006
52.223-5	Pollution Prevention and Right-To-Know Information.	AUG 2003
52.223-6	Drug-Free Workplace.	MAY 2001
52.225-13	Restrictions on Certain Foreign Purchases.	JUNE 2008
52.227-1	Authorization and Consent, Alternate I	APR 1984
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement.	DEC 2007
52.227-14	Rights in Data - General.	DEC 2007
52.227-16	Additional Data Requirements.	JUN 1987
52.229-3	Federal, State and Local Taxes	APR 2003
52.232-7	Payments under Time-and-Materials and Labor-Hour Contracts with Alternate I	FEB 2007
52.232-9	Limitation on Withholding of Payments.	APR 1984
52.232-16	Progress Payments.	APR 2003
52.232-17	Interest.	OCT 2008
52.232-18	Availability of Funds.	APR 1984
52.232-23	Assignment of Claims.	JAN 1986
52.232-25	Prompt Payment.	OCT 2008
52.232-33	Payment by Electronic Funds Transfer-Central Contractor Registration	OCT 2003
52.233-1	Disputes.	JUL 2002
52.233-3	Protest after Award.	AUG 1996
52.237-3	Continuity of Services.	JAN 1991
52.242-1	Notice of Intent to Disallow Costs.	APR 1984
52.242-13	Bankruptcy.	JUL 1995
52.243-1	Changes—Fixed Price. Alternate I	APR 1984
52.243-3	Changes—Time-and-Materials or Labor-Hours.	SEP 2000
52.244-2	Subcontracts.	JUN 2007
52.244-5	Competition in Subcontracting.	DEC 1996
52.246-23	Limitation of Liability.	FEB 1997
52.249-2	Termination for Convenience of the Government (Fixed-Price).	MAY 2004
52.249-4	Termination for Convenience of the Government (Services) (Short Form).	APR 1984
52.249-5	Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)	SEPT 1996

## **I.2 FAR Clauses in Full Text**

### **52.217-8 Option to Extend Services (NOV 1999)**

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within the term of the contract.

### **52.217-9 Option to Extend the Term of the Contract (MAR 2000)**

(a) The Government may extend the term of this contract by written notice to the Contractor at any time within the term of the contract.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 5 years.

### **52.223-10 Waste Reduction Program (AUG 2000)**

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

“Recycling” means the series of activities, including collection, separation, and processing, by which products or other materials are recovered from the solid waste stream for use in the form of raw materials in the manufacture of products other than fuel for producing heat or power by combustion.

“Waste prevention” means any change in the design, manufacturing, purchase, or use of materials or products (including packaging) to reduce their amount or toxicity before they are discarded. Waste prevention also refers to the reuse of products or materials.

“Waste reduction” means preventing or decreasing the amount of waste being generated through waste prevention, recycling, or purchasing recycled and environmentally preferable products.

(b) Consistent with the requirements of Section 701 of Executive Order 13101, the Contractor shall establish a program to promote cost-effective waste reduction in all operations and facilities covered by this contract. The Contractor’s programs shall comply with applicable Federal, State, and local requirements, specifically including Section 6002 of the Resource Conservation and Recovery Act (42 U.S.C. 6962, et seq.) and implementing regulations (40 CFR Part 247).

### **I.3 Health and Human Services Acquisition (HHSAR) Regulation by Reference**

Full text of HHSAR clauses at this address: [www.hhs.gov/oamp/policies](http://www.hhs.gov/oamp/policies)

352.228-7	Insurance - Liability to third persons, Alternate 1.	DEC 1991
352.233-70	Litigation and claims.	JAN 2006
352.242-71	Final decisions on audit findings.	APR 1984
352.249-14	Excusable delays.	JAN 2006
352.270-7	Paperwork Reduction Act.	JAN 2006

### **I.4 Health and Human Services Acquisition (HHSAR) Regulation Clauses in Full text**

#### **352.202-1 Definitions. (DEC 2006)**

(a) In accordance with 52.202-1(a)(1), substitute the following as paragraph (a):

“(a) The term “Secretary” or “Head of the Agency” (also called “Agency Head”) means the Secretary, Deputy Secretary, or any Assistant Secretary, Administrator or Commissioner of the Department of Health and Human Services; and the term “his/her duly authorized representative” means any person, persons, or board authorized to act for the Secretary.”

(b) In accordance with 52.202-1(a)(1), add the following paragraph (h):

“(h) The term “COTR” means the person who monitors the technical aspects of contract performance. The COTR is not authorized to issue any instructions or directions which cause any increase or decrease in the scope of work which will result in the increase or decrease in the price of this contract, or changes in the delivery schedule or period of performance of this contract. If applicable, the COTR is not authorized to receive or act upon any notification or revised cost estimate provided by the Contractor in accordance with the Limitation of Cost or Limitation of Funds clauses of this contract.”

#### **352.224-70 Confidentiality of Information (JAN 2006)**

(a) Confidential information, as used in this clause, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

(b) The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the

performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

(c) If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

(d) Confidential information, as defined in paragraph (a) of this clause, shall not be disclosed without the prior written consent of the individual, institution, or organization.

(e) Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this clause, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

(f) Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

(g) The provisions of paragraph (d) of this clause shall not apply to conflicting or overlapping provisions in other Federal, State, or local laws.

#### **352.232-9 Withholding of Contract Payments (JAN 2006)**

Notwithstanding any other payment provisions of this contract, failure of the Contractor to submit required reports when due or failure to perform or deliver required work, supplies, or services, may result in the withholding of payments under this contract unless such failure arises out of causes beyond the control, and without the fault or negligence of the Contractor as defined by the clause entitled "Excusable Delays" or "Default", as applicable. The Government shall immediately notify the Contractor of its intention to withhold payment of any invoice or voucher submitted.

#### **352.270-6 Publications and Publicity (JAN 2006)**

(a) Unless otherwise specified in this contract and the Confidentiality of Information clause is included, the Contractor is encouraged to publish the results of its work under this contract. A copy of each article submitted by the Contractor for publication shall be promptly sent to the COTR. The Contractor shall also inform the COTR when the article or other publication is published, and furnish a copy of it as finally published.

(b) The Contractor shall include in any publication resulting from work performed under this contract a disclaimer reading as follows:

"The views expressed in written conference materials or publications and by speakers and moderators at HHS-sponsored conferences, do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade

names, commercial practices, or organizations imply endorsement by the U.S. Government.”

(c) Unless authorized by the COTR, the Contractor shall not display the HHS logo on any conference materials or publications.

**352.270-10 Anti-lobbying (JAN 2006)**

Pursuant to the current HHS annual appropriations act, except for normal and recognized executive-legislative relationships, the Contractor shall not use any HHS contract funds for (i) publicity or propaganda purposes; (ii) 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 legislature, except in presentation to the Congress or any State legislature itself; or (iii) payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

**I.5 52.216-18 Ordering. (OCT 1995)**

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from September 23, 2009 through September 22, 2014.

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) If mailed, a delivery order or task order is considered “issued” when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

**I.6 52.216-22 Indefinite Quantity. (OCT 1995)**

(a) This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.

(b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the “maximum.” The Government shall order at least the quantity of supplies or services designated in the Schedule as the “minimum.”

(c) Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

(d) Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; *provided*, that the Contractor shall not be required to make any deliveries under this contract after 60 months.

#### **I.7 52.216-19 Order Limitations. (OCT 1995)**

(a) *Minimum order.* When the Government requires supplies or services covered by this contract in an amount of less than twenty thousand, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) *Maximum order.* The Contractor is not obligated to honor—

- (1) Any order for a single item in excess of twenty million;
- (2) Any order for a combination of items in excess of twenty million; or
- (3) A series of orders from the same ordering office within two weeks that together call for quantities exceeding the limitation in paragraph (b)(1) or (2) of this section.

(c) If this is a requirements contract (*i.e.*, includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.

(d) Notwithstanding paragraphs (b) and (c) of this section, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 7 days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.