

PART I – THE SCHEDULE

SECTION A - STANDARD FORM 26

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. CONSIDERATION AND PAYMENT

The Contractor shall provide the services described in Section C, Description/Specification/Work Statement. Except as otherwise specified in the contract, the Contractor shall furnish the necessary personnel, materials, services, facilities, and otherwise do all things necessary for or incident to the performance of the work set forth herein.

In consideration of satisfactory performance of the work described in the Statement of Work, and the satisfactory acceptance by the Government of the deliverables, the Contractor shall be paid in accordance with the following schedule set forth below.

**Firm Fixed Price Type Contract**

Description	Quantity	Unit	Total Firm Fixed Price
E-Consent Trial: Education, Collection, & Evaluation of Patient Choice in the Electronic Exchange of Health Information.	1	JB	\$1,239,908.99

B.2. FIRM FIXED PRICE PAYMENT SCHEDULE

The Contractor shall submit a total of five (5) invoices, each being twenty percent (20%) of the total contract amount. The Contractor shall submit an individual invoice after the COTR accepts each of the following Contractor deliverables associated with specific project tasks: (1) Task 5, (2) Task 7; (3) Task 10; (4) Task 11; and (5) Task 13. Two (2) hardcopies will be submitted directly to the COTR for certification. The COTR will forward the certified invoice to the Procurement Office for processing. The Contractor shall notify the COTR and Contracting Officer when 75% and 90% of the effort (either in hours and dollars) are expended, if applicable.

## SECTION C- DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

### TITLE:

### **E-Consent Trial: Education, Collection, & Evaluation of Patient Choice in the Electronic Exchange of Health Information**

#### C.1 BACKGROUND

One of the key goals of the Federal Health Information Technology Strategic Plan (Strategic Plan) is to inspire consumer trust and confidence in health information technology (health IT) and electronic health information exchange (eHIE) by protecting the confidentiality and integrity of health information through appropriate and enforceable federal policies. Informed patient choice is one way to ensure a trust relationship with patients for the success of electronic health information exchange. Recent recommendations by the Health Information Technology Policy Committee (HITPC) stress the importance of *meaningful* choice: that the patient understand how information will be shared and with whom and the potential consequences of deciding whether to share information or not.<sup>1</sup> The recommendations also note that it is the person who has the treating relationship with the patient who is responsible for educating patients regarding how information will be shared and with whom, as well as obtaining and tracking patient choice.<sup>2</sup> The recommendations further state that The Office of the National Coordinator for Health Information Technology (ONC) should provide resources and educational materials to providers to demonstrate and implement meaningful choice for patients.<sup>3</sup> These recommendations raise a number of issues that require additional exploration including:

- What background information do patients desire and need when making decisions regarding electronically sharing their health information?
- Do patients understand the choices they make? How can we determine the level of their understanding?
- Are there means of electronically facilitating, obtaining, and recording consent to assist health care providers who are engaged in this process?

We have little research with respect to determining whether patients are adequately informed to understand the choices they make with respect to sharing health information. However, research in the context of obtaining informed consent to health treatment provides some useful information. Research indicates that efforts to collect informed consent for treatment from

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<sup>1</sup> See Health IT Policy Committee, Privacy and Security Tiger Team. *Letter to David Blumenthal, Chairman of the Office of the National Coordinator for Health IT*, Aug. 19, 2010. Available at: [http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS\\_0\\_0\\_6011\\_1815\\_17825\\_43/http%3B/wci-pubcontent/publish/onc/public\\_communities/\\_content/files/hitpc\\_transmittal\\_p\\_s\\_tt\\_9\\_1\\_10.pdf](http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_0_6011_1815_17825_43/http%3B/wci-pubcontent/publish/onc/public_communities/_content/files/hitpc_transmittal_p_s_tt_9_1_10.pdf).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

patients often are inadequate.<sup>4</sup> For example, in one review of informed consent documents from randomly selected hospitals, the documents examined were shown to have very limited educational value.<sup>5</sup> The ability to obtain meaningful consent to share health information presents similar challenges.

Research has identified some of the challenges with respect to obtaining patient choice preferences for the purpose of electronic exchange, including:

1. Establishing policies and procedures to guide the consent process;
2. Educating both patients (about the exchange) and providers (about their responsibilities with respect to consent management);
3. Developing methods and materials to support the education process; and
4. Developing methods and materials to obtain actual consent.<sup>6</sup>

According to studies, a paper form is currently the most widely used method of collecting consent; however, it is generally accompanied by some personal interaction with the individual or entity obtaining consent, either in person or by telephone.<sup>7</sup> Research indicates that any method used to collect consent must be capable of recording the patient's preference in a manner that will continually reflect the patient's preference and is actionable by other parties, thus enabling the patient's preference to be honored. This is likely to prove difficult with respect to paper-based consent in an electronic exchange environment.<sup>8</sup>

Concerns about the limitations of paper-based consent in the electronic exchange environment have led to support for electronic methods of obtaining and managing consent.<sup>9</sup> To date, some providers are relying on electronic consent to capture a patient's consent for particular medical procedures, for example, select U.S. Department of Veterans Affairs (VA) centers.<sup>10</sup> Their experience indicates that when accompanied by clear communication, e-consent can facilitate patient understanding of the procedure and ease tracking of consent.<sup>11</sup> Also, a survey of patients in the Atlanta VA medical center found that 96% of the patients preferred the use of an electronic consent process to collect and document consent.<sup>12</sup> In addition to work by the VA, the

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<sup>4</sup> Krumholz, Harlan M., MD, SM. "Informed consent to promote patient-centered care." *JAMA*. Vol. 303, No. 12, Mar. 24, 2010.

<sup>5</sup> Bottrell MM, Alpert H, Fischbach RL, Emanuel LL. "Hospital informed consent for procedure forms: facilitating quality patient-physician interaction." *Arch Surg*. 2000;135(1):26-33.

<sup>6</sup> Goldstein, M.M. and A.L. Rein. *Consumer Consent Options for Electronic Health Information Exchange: Policy Considerations and Analysis*, Mar. 2010, 34 – 35, available at: [http://healthit.hhs.gov/portal/server.pt/community/healthit\\_hhs\\_gov\\_privacy\\_and\\_security/1147](http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_privacy_and_security/1147).

<sup>7</sup> Goldstein and Rein, 37.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> Spotswood, S. "VA Patient Consent Goes Electronic," *U.S. Medicine Information Central*, Feb. 2005.

<sup>11</sup> *Id.*

<sup>12</sup> Issa MM, Setzer E, Charaf C, et al. "Informed versus uninformed consent for prostate surgery: the value of electronic consents". *J Urol*. Vol. 176, 694 – 699. August, 2006.

Healthcare Information Technology Standards Panel (HITSP) has created standards for an electronic consent directive which would, among other things, allow for the electronic creation and exchange of consent preferences.<sup>13</sup>

With the growing interest in electronic consent mechanisms, and considering the role of meaningful patient choice in the success of eHIE, it is important to look carefully at the issues surrounding electronic consent. Research to date on this topic is limited, and in particular, the educational component of electronic consent must be explored in more detail. It is critical to understand what information patients desire and need when making decisions regarding their health information as well as what information they consider relevant for patient choice regarding the exchange of their health information in an electronic environment. Also, as patients become more engaged in their health care – and in an effort to keep patients more engaged – communication with patients assumes even greater importance.

In addition, it is essential to understand issues related to presenting educational materials to patients about the realities associated with the electronic exchange of health information and patient choice with respect to sharing their health information. The efforts by the VA to adopt an electronic consent system are frequently cited, and evaluation to date indicates the value of developing such a system.<sup>14</sup> However, the VA's system and many other systems in use today are primarily being applied with respect to consent for health procedures or treatment and not for electronic health information exchange. It will be important to address the unique challenges of collecting and tracking patient choice regarding sharing their health information in an electronic environment, where information exchanged between health care providers must indicate a patient's meaningful, informed choice and enable the patient choice to be honored.

## C.2. PURPOSE

The Office of the Chief Privacy Officer (OCPO) within ONC proposes to award a contract to

- a. Use innovative ways to
  - i. Educate and inform individuals of their option to give individual choice (e.g., automate informed consent process, patient-centered decision making process) in a clinical setting to share their health information electronically; and
  - ii. Ensure that individuals are knowledgeable participants in decisions about the sharing their electronic health information in a clinical environment.

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<sup>13</sup> U.S. Department of Health and Human Services, Office of the National Coordinator for Health IT (ONC). *Consumer Preferences Draft Requirements Document*, October 5, 2009, at 34, available at: [http://www.healthit.hhs.gov/portal/server.pt/gateway/PTARGS\\_0\\_10779\\_891071\\_0\\_0\\_18/20091005\\_Consumer%20Preferences\\_Draft\\_Requirements\\_Document.pdf](http://www.healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10779_891071_0_0_18/20091005_Consumer%20Preferences_Draft_Requirements_Document.pdf). See also, Goldstein, M.M. and A.L. Rein. *Consumer Consent Options for Electronic Health Information Exchange: Policy Considerations and Analysis*,” 39 (noting that the HITSP consent standard is not widely implemented at this time, and it is unclear how the standard would operate in practice and to what extent it may impact provider workflow).

<sup>14</sup> Bottrell MM, Alpert H, Fischbach RL, Emanuel LL. "Hospital informed consent for procedure forms: facilitating quality patient-physician interaction." *Arch Surg*. 2000;135(1):26-33.

- b. Explore and evaluate ways of electronically obtaining and recording meaningful and informed choice from individuals in a clinical setting, regarding sharing their electronic health information.

The project is designed to help identify some innovative best practices in ensuring that any choices patients make with respect to sharing their health information are indeed, meaningful: i.e., patients are adequately educated about issues that are important to them, and that they understand the choices they make as well as the consequences of those choices.

### C.3 STATEMENT OF WORK

The contractor shall perform the following tasks: To achieve the purpose stated above, the Contractor, in consultation with OCPO, shall

#### **C.3.1. Task 1. Project Kick-Off Meeting**

No Later Than (NLT) three weeks of Effective Date of the Contract (EDOC), an initiation meeting will be held between key contractor's personnel and the Contracting Officer Technical Representative (COTR) and personnel identified by ONC. The purpose of the meeting is to review project requirements and options, ensure common understanding of roles and responsibilities, and discuss relevant ONC activities and initiatives. In consultation with the COTR, the Contractor shall prepare the agenda and hand-outs for the kick-off meeting, take notes, and prepare meeting minutes. Discussion topics shall include, but are not necessarily limited to, the purpose of the project, technical approach, deliverables, and reporting requirements. At this meeting, the Contractor will also present an outline of the project work plan.

#### **C.3.2. Task 2. Project Approach & Work Plan**

**Subtask 3.2.1.** The Contractor shall develop a comprehensive work plan, delivery schedule, and timeline for completing all tasks for this project. The Contractor shall deliver an overall Project Work Plan (PWP) that details the life cycle of the project, including phases, iterations, and key milestones including integration points and procurement events, scope, cost, schedule, risks, and quality assurance. The work plan must include a "Letter of Support" of the proposed work plan from the planned partner site.

The PWP shall contain a deliverables-based Work Breakdown Structure (WBS) that accurately and completely captures all development work specified in the Statement of Work and any other documentation provided as a companion to the request for proposal (RFP). The WBS shall identify dependencies among the activities as well as dependencies with

other contract activities. The WBS shall be resource-loaded and accompanied by a time-phased budget (budgeted cost of work scheduled (BCWS)).

**Subtask 3.2.2.** The Contractor shall submit the project work plan to the COTR for review and approval.

### **C.3.3. Task 3. Identify & Form Collaborative Partnership with Existing Active Health Site**

**Subtask 3.3.1.** The Contractor shall identify an existing clinical setting/situation/site in which electronic health information is exchanged (e.g., Provider-to-Provider Exchange, Health Information Exchange (HIE), Accountable Care Organization (ACO), Beacon Community, Health IT Regional Extension Center (REC), State HIE grantee, one Covered Entity system) to serve as a partner/site for e-consent information gathering, e-consent pilot, and evaluation (Task 5 through 12).

**Subtask 3.3.2.** The Contractor shall submit the identified proposed partner to COTR for review and approval.

### **C.3.4. Task 4. Devise a Means of Obtaining Well-Balanced Patient Input**

**Subtask C.3.4.1.** Relying on patient population at the clinical partner site, the Contractor shall devise a means for obtaining patient input into development, use, and evaluation of Tasks 5 through 12, and means used, e.g., focus group, should be representative of population of clinical partner, to extent possible.

**Subtask C.3.4.2.** The Contractor shall submit and review with the COTR the brief written description of process, method of obtaining patients to participate, and how well process represents population.

### **C.3.5. Task 5. Identify Key Informational Elements Regarding Exchange of Health Information and Patient Choice**

**Subtask C.3.5.1.** Using patient input process, develop and implement a general means of describing or informing identified patients of how health information is or will be electronically shared in the clinical environment, as well as models of patient choice and exchange.

**Subtask C.3.5.2.** Gather and analyze patients' expectations and perspectives regarding the information they would desire and or need prior to making the decision to share their health information to participate in the exchange of their health information in an electronic environment.

**Subtask C.3.5.3.** The Contractor shall submit and review with the COTR the general education material targeted at patients regarding the exchange of health information in a clinical setting as well as models of patient choice and exchange.

**Subtask C.3.5.4.** Determine key elements/factors to educate individuals on, to ensure patients understand their option to give individual choice and understand the implications of their choice decision.

**Subtask C.3.5.5.** The Contractor shall submit and review with the COTR the key elements/factors identified and reasons patients need to be informed of, in order to make an informed choice regarding the sharing of their health information electronically.

### **C.3.6. Task 6. Consumer Content/Educational Material Development**

**Subtask C.3.6.1.** The Contractor shall develop content to educate patients on patient choice regarding sharing of electronic health information in a clinical setting, catering to key elements identified in Task 4.0.

**Subtask C.3.6.2.** The Contractor shall develop supporting reference/explanatory information for questions to provide patients with more detailed explanation, if patients select to obtain further information about a particular area (e.g., Reference/Decision Support Tool).

**Subtask C.3.6.3.** The Contractor shall review content/educational material and supporting reference/explanatory information with COTR prior to submitting final E-Consent Content/Educational Material document.

### **C.3.7. Task 7. Develop Means of Evaluating Patient Satisfaction with and Knowledge Obtained from Educational Material Used in E-Consent Pilot**

**Subtask C.3.7.1.** Identify approach and means of evaluating patient satisfaction with and knowledge obtained from/understanding of educational material developed in Task 6.0 that will be used in the e-Consent pilot (Task 11).

**Subtask C.3.7.2.** Prior to deploying the e-Consent pilot, the Contractor shall submit approach to and method of evaluating patient satisfaction and knowledge to COTR for review and approval.

### **C.3.8. Task 8. Script/Authoring Interface**

**Subtask C.3.8.1.** The Contractor shall author question script, answers, alternatives and control logic (e.g., XML) about patient choice, focusing on key elements identified in Task 5.0.

**Subtask C.3.8.2.** Interface should be developed to maximize patient understanding of material being presented.

**Subtask C.3.8.3.** The Contractor shall develop follow-up questions to ensure patients understand material being presented to them.

**Subtask C.3.8.4.** Provide for the capability to capture and record valid patient choice regarding sharing health information in an electronic environment (e.g., e-signature).

**Subtask C.3.8.5.** The Contractor shall develop material using an open accessible language.

**Subtask C.3.8.6.** The Contractor shall submit to and review with COTR the script, questions, answers, alternatives and control logic.

### **C.3.9. Task 9. Graphical User Interface (GUI) Design**

**Subtask C.3.9.1.** In coordination with the ONC-Standards & Interoperability (S&I) Framework, the Contractor shall select an effective Graphic User Interface (GUI) Design/Development platform, and then design an intuitive GUI that supports interactive specification of identified patient choice regarding sharing electronic health information.

**Subtask C.3.9.2.** Plain English text, familiar graphics, and easy screen navigation that enables users to understand individual patient choice options and constraints.

**Subtask C.3.9.3.** Software shall be able to read any description so if content changes, software does not have to be modified.

**Subtask C.3.9.4.** Template and formats for reference information/decision-support tool that explain options, constraints, and consequences.

**Subtask C.3.9.5.** The Contractor shall submit and review the GUI Design, code set, and implementation guide with the COTR.

### **C.3.10. Task 10. Machine Readable Text**

**Subtask C.3.10.1.** Format and present developed content/educational and informative material to allow questions to flow in a logical manner.

**Subtask C.3.10.2.** The Contractor shall stay abreast of and coordinate with other ONC existing patient choice related activities, where appropriate.

**Subtask C.3.10.3.** The Contractor shall work in collaboration with ONC's S & I Program and use standards for patient choice as specified by ONC's S & I Program. Use existing standards for

patient choice, where applicable. Develop common way of describing patient choice that is machine readable and flexible (e.g., Integrating the Healthcare Enterprise (IHE) language for consent management, HITSP HL 7).

**Subtask C.3.10.4.** The Contractor shall submit the machine readable text/code set and implementation guide with the COTR.

### **C.3.11. Task 11. Deploy E-Consent Pilot**

**Subtask C.3.11.1.** The Contractor shall conduct e-Consent Pilot for 3 – 6 months with approved partner active health care site.

**Subtask C.3.11.2.** The Contractor shall use material, means, and activities identified and approved in Task 3.0 – 10.0 to conduct e-Consent Pilot.

**Subtask C.3.11.3.** The Contractor shall coordinate with ONC’s S & I program’s patient choice activities, using cross-piloting where appropriate.

**Subtask C.3.11.4.** The Contractor shall preview the e-Consent Pilot with the COTR before launching the pilot at the partner site.

### **C.3.12. Task 12.0: Evaluate Patient Understanding & Satisfaction**

**Subtask C.3.12.1.** The Contractor shall evaluate patient understanding regarding patient choice provided through the e-Consent pilot, regarding the key elements identified in Task 5.0.

**Subtask C.3.12.2.** Evaluate if patients received meaningful, informed patient choice, based on the key elements identified in Task 5.0, provided through the e-Consent pilot (E.g., opt-in v. opt-out; patients understand they have given/not given permission for a provider to share electronic health information with other people in a clinical setting; understanding of implication of their patient choice to disclose electronic health information).

**Subtask C.3.12.3.** The Contractor shall evaluate patient satisfaction with the education material provided through the e-Consent pilot, regarding the key elements identified in Task 5.0.

**Subtask C.3.12.4.** The Contractor shall submit and review summary document of evaluation of patient understanding and satisfaction with the COTR.

### **C.3.13. Task 13.0: Provide and Present Written E-Consent Project Report**

**Subtask C.3.13.1.** Prior to writing the final e-consent project report, the Contractor shall submit an outline and overall report structure to the COTR for review and approval.

**Subtask C.3.13.2.** In accordance with the approved structure, the Contractor shall develop a report suitable for publication that summarizes the process, accomplishments, and results of the e-consent project. In addition, the report should include project key findings, lessons learned, and recommendations for path forward to operationalize patient choice in the electronic exchange of health information.

**Subtask C.3.13.3.** The Contractor shall review and brief the COTR on the e-consent project report.

**Subtask C.3.13.4.** If required by the COTR, the Contractor shall brief high level Agency/other officials on the project. This will encompass preparation of all briefing materials including visual aids.

#### **C.3.14. Task 14. Conduct Regular Status Meetings with ONC**

**Subtask C.3.14.1.** Schedule and conduct regular status meetings, at least every two weeks and at the request of ONC. Provide agendas, deliver status update report (COTR approved format), and keep meeting minutes. The purpose of the meetings will be to review work progress, specific deliverables, and future plans under the contract. The work plan may be revised based on identified issues, risk mitigation strategies, and decisions made at these meetings.

#### **C.3.15. Task 15. Monthly Progress Report**

**Subtask C. 3.15.1.** The Contractor shall submit to the COTR written monthly technical reports describing progress against approved milestones, major activities of the project, beginning in the second month following the effective date. Each monthly progress report shall list, by major task, project activities of the past month, the cost of those activities, the anticipated next month's activities, problems encountered and proposed solutions, milestones, any dependencies related to the government's upcoming responsibilities, and any other information which has a significant impact on ongoing or planned activities or costs. The report should also compare progress and resource expenditures to the original schedule and budget and provide explanations for any variances, assess whether the current total estimated contract cost is sufficient to complete the contract, and describe significant changes in the Contractor's operational personnel. The monthly progress report shall be delivered to the COTR no later than ten work days after the end of the reporting month. The Monthly Progress Report shall include, at a minimum, prior month's activities by task and activity, such as:

- a. Summaries of meetings and areas of concentration for the upcoming month;
- b. Issues of concern that require ONC action;
- c. Updates with regard to quality assurance;
- d. Any unresolved issues from the prior month; and
- e. Any other information the COTR may request or require.

**Subtask C.3.15.2.** The monthly progress report and monthly financial report should have the same reporting periods so that activities described in the status report align with the costs on the monthly financials.

### **C.3.16. Task 16. Monthly Financial Report/Labor Matrix and Monthly Work Plan**

**Subtask C.3.16.1.** The Contractor shall provide a monthly financial report to the COTR that is in a format that is pre-approved by the COTR. The monthly financial report should include a) actual costs incurred for reporting period, b) costs incurred under contract year-to-date, and c) budgeted costs for the reporting period, d) estimated costs by month for the remainder of the contract performance period, broken down by tasks, and subtasks, as appropriate.

**Subtask C.3.16.2.** The monthly financial report and monthly progress report should have the same reporting periods so that activities described in the progress report align with the costs in the monthly financial report.

## **C.4 Misconduct / Disruption of Services**

At any time during the performance of this contract, the COTR or OPDIV Department Head may request that the contractor immediately remove any contract employee whose actions, or impaired state, results in a disruption to the workforce. The Contractor must replace the provider within 30 days, or as agreed upon with the COTR.

The Government reserves the right to test contract personnel prior to performing services and/or at any time during the contract performance period to ensure that they possess the necessary contract-required skills. Any contract personnel found to be unacceptable in administering skills required by the contract shall be immediately released from duty by the on-duty supervisor or COTR. The COTR or OPDIV designated official shall immediately notify the Contracting Officer, who will direct the Contractor to provide a replacement.

**SECTION D - PACKAGING AND MARKING**

D.1. PACKAGING

All deliverables shall be preserved, packaged, and packed in accordance with normal commercial practices to meet the packing requirements of the carrier including that which is necessary to prevent deterioration and damages due to the hazards of shipping, handling, and storing.

D.2. MARKING

Each package/container shall be delivered to the address shown in Section F.3 entitled “Deliverable Schedule” and shall be clearly marked as follows:

- A. Name of Contractor;
- B. Contract Number;
- C. Description of Items Contained Therein; and
- D. Consignee’s Name and Address.

**SECTION E - INSPECTION AND ACCEPTANCE**

E.1 INSPECTION AND ACCEPTANCE

All work under this contract is subject to inspection and final acceptance by the Contracting Officer or duly authorized representative of the Government

The Government Contracting Officer's Technical Representative (COTR) is a duly authorized representative of the Government and is responsible for inspection and acceptance of all items to be delivered under this contract.

E.2 FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE. (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <https://www.acquisition.gov/far/index.html>

FAR Clause No.

Date and Title

52.246-4

INSPECTION OF SERVICES - FIXED-PRICE.  
(AUG 1996)

**SECTION F - DELIVERIES OR PERFORMANCE**

F.1 PERIOD OF PERFORMANCE

The period of performance shall be September 30, 2011 through March 31, 2013, unless changed by modification to the contract.

F.2 DELIVERABLE SCHEDULE

All deliverable required by this contract shall be delivered to the Contracting Officer and COTR for review and approval.

The Contractor shall prepare and submit the following deliverables on the required due date, in the quantity and format stated (if applicable), to the COTR.

DELIVERABLE	DUE DATE
<b>C.3.1: Task 1. Project Kick-off Meeting</b>	
Kick-Off Meeting Agenda, Meeting Material, Outline of E-Consent project work plan, and meeting minutes	NLT 3 weeks after award date of contract
<b>C.3.2: Task 2. Project Approach &amp; Work Plan</b>	
Project Approach and Work Plan with associated Delivery Schedule and Timeline; “Letter of Support” of the proposed work plan from the planned partner site.	NLT 4 weeks after ADOC
<b>C.3.3: Task 3. Identify &amp; Form Collaborative Partnership with Existing Active Health Site</b>	
Proposed collaborative partnership with existing health site for e-Consent project	NLT 3 weeks after ADOC
<b>C.3.4: Task 4. Devise a Means of Obtaining Well-Balanced Patient Input</b>	
Brief written description of process and method of obtaining patients to participate, as well as how well process represents population	NLT 6 weeks after ADOC
<b>C.3.5: Task 5. Identify Key Informational Elements Regarding Exchange of Health Information and Patient Choice</b>	
<b>Subtask C.3.5.3.</b> General educational material targeted at patients regarding the exchange of health information in a clinical setting as well as models of patient choice and exchange.	NLT 8 weeks after ADOC
<b>Subtask C.3.5.4.</b> Identification of key elements/factors and reasons	NLT 12 weeks after

patients need to be informed of in order to make an informed choice regarding the sharing of their health information electronically.	ADOC
<b>C.3.6: Task 6. Consumer Content/Educational Material Development</b>	
Content/Education Material document and supporting/explanatory information for E-Consent Pilot	NLT 20 weeks after ADOC
<b>C.3.7: Task 7. Develop Means of Evaluating Patient Satisfaction with and Knowledge Obtained from Educational Material used in E-Consent Pilot</b>	
Briefing on the approach to and method of evaluation of patient satisfaction and knowledge obtained from educational material used in E-Consent Pilot	NLT 24 weeks after ADOC
<b>C.3.8: Task 8. Script/Authoring Interface</b>	
Script, questions, answers, alternatives, and control logic	NLT 28 weeks after ADOC
<b>C.3.9: Task 9. Graphical User Interface (GUI) Design</b>	
GUI Design, code-set, and implementation guide for e-Consent Pilot	NLT 36 weeks after ADOC
<b>C.3.10: Task 10. Machine Readable Text</b>	
Machine Readable Text/Code Set and Implementation Guide	NLT 36 weeks after ADOC
<b>C.3.11: Task 11. Deploy E-Consent Pilot</b>	
Preview of e-Consent Pilot with the PO before launching the pilot at the partner site	NLT 48 weeks after ADOC
<b>C.3.12: Task 12. Evaluate Patient Understanding &amp; Satisfaction</b>	
Summary Document of Evaluation of Patient Understanding and Satisfaction with educational material and E-Consent Pilot	NLT 80 weeks after ADOC
<b>C.3.13: Task 13. Provide and Present Written E-Consent Project Report</b>	
<b>Subtask C.3.13.1:</b> Proposed Outline and Overall Report Structure	NLT 78 weeks after ADOC
<b>Subtask C.3.13.3:</b> Final E-Consent Project Report	NLT 84 weeks after ADOC
<b>C.3.14: Task 14. Conduct Regular Status Meetings with ONC</b>	
Agendas, Status Update Report, & Meeting Minutes	At least every 2 weeks
<b>C. 3.15: Task 15. Monthly Progress Report</b>	
Monthly Progress Report	Monthly
<b>C.3.16: Task 16. Monthly Financial Report</b>	
Monthly Financial Report	Monthly

F.3 QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)

**Quality Assurance Surveillance Plan**

The Contracting Officer Technical Representative will review, for completeness, preliminary or draft products that the Contractor submits, and may return them to the Contractor for correction. Absence of comments by the COTR will not relieve the Contractor of the responsibility for complying with the requirements of this work statement. Final approval and acceptance of products required herein shall be by letter of approval and acceptance by the COTR. The COTR shall not construe any letter of acknowledgment of receipt of products as a waiver of review, or as an acknowledgment that a product is in conformance with this work statement. Any approval given during preparation of a product, or approval for shipment shall not guarantee the final acceptance of the completed product.

Required Tasks	Task Standard	Method of Surveillance	Standard to be Met	Deduction
<b>C.3.1: Task 1. Project Kick-Off Meeting</b>	Meeting materials, outline of project work plan, and meeting minutes	COTR reviews the agenda, kick-off meeting materials, project work plan outline, and meeting minutes	Final is comprehensive and includes COTR’s comments, is error free, and submitted on time	Up to 1% of invoice #1
<b>C.3.2: Task 2. Project Approach &amp; Work Plan</b>	The Project Work Plan (PWP) contains a detailed strategy and technical approach for successfully accomplishing the objectives/outcomes in the SOW and is consistent with the required deliverables; associated delivery schedule and timeline; “Letter of Support” of the proposed work plan from the planned partner site.	COTR reviews the PWP, timeline, and “Letter of Support” for accuracy and suitability and provides feedback, and accept or rejects	Final is comprehensive and includes COTR’s comments, is error free and submitted on time. Updates are delivered as required	Up to 5% of invoice #1
<b>C.3.3: Task 3. Identify &amp; Form Collaborative Partnership with Existing Site</b>	Identified clinical setting/situation/site in which electronic health information is exchanged to serve as a partner/site for e-consent information gathering source and pilot site is an appropriate site as described in Task 3.0	COTR reviews the proposed partner site and provides feedback, accepts or rejects	Collaborative Partnership site is identified and presented to and approved by COTR as required	Up to 5% of invoice #1

Required Tasks	Task Standard	Method of Surveillance	Standard to be Met	Deduction
	above.			
<b>C.3.4: Task 4. Devise a Means of Obtaining Well-Balanced Patient Input</b>	Drafted brief written description of process and method of obtaining patients to participate, as well as how well process represents population	COTR reviews written description of process and method, accepts or rejects	Devised means of obtaining well—balanced patient input is developed and presented to and approved by COTR as required	Up to 5% of invoice #1
<b>C.3.5: Task 5. Identify Key Informational Elements Regarding Exchange of Health Information and Patient Choice</b>	Developed General Education material to gather patient input; Elements/topics are well developed and appropriate	COTR reviews general education material; elements for suitability, provides feedback, accepts or rejects	Final elements include COTR’s feedback and submitted as required	Up to 5% of invoice #1
<b>C.3.6: Task 6. Consumer Content/ Educational Material Development</b>	Content material is sufficient for educating patients on choices and key elements identified in Task 5; supporting reference/explanatory information provides sufficiently detailed information	COTR reviews material for suitability, accuracy, and thoroughness provides feedback, accepts or rejects	Final material include COTR’s feedback and submitted as required	Up to 5% of invoice #2
<b>C.3.7: Task 7. Develop Means of Evaluating Patient Satisfaction with and Knowledge obtained from Educational Material used in E-Consent Pilot</b>	Means of evaluating patient satisfaction with and knowledge obtained through E-Consent Pilot is comprehensive and sufficient for evaluating patient satisfaction	COTR reviews evaluation criteria for suitability, accuracy, and thoroughness provides feedback, accepts or rejects	Final material include COTR’s feedback and submitted as required	Up to 5% of monthly invoice 2

Required Tasks	Task Standard	Method of Surveillance	Standard to be Met	Deduction
<b>C.3.8: Task 8. Script/Authoring Interface</b>	Authored question script, answers, alternatives, and control logic about patient choice, focusing on key elements identified in Task 5.0 and 6.0 and educational material	COTR reviews the script that it as specified in Task 8.0 above, provides feedback, accepts or rejects	Final version for Pilot includes COTR's feedback and submitted on time	Up to 5% of invoice #3
<b>C.3.9: Task 9. Graphical User Interface (GUI) Design</b>	Designed GUI platform is intuitive and will support interactive specification of patient choice; developed corresponding code set and implementation guide; coordinated with ONC S&I Framework	COTR reviews the GUI design to ascertain that it is designed as specified in Task 9.0 above, provides feedback, accepts or rejects	Final prototype for e-Consent Pilot includes COTR's feedback and submitted on time	Up to 5% of invoice #3invoice
<b>C.3.10: Task 10. Machine Readable Text</b>	Formatted and developed content/educational and informative material, in coordination with ONC's Standards & Interoperability Program, that allows questions to flow in a logical manner. Worked in collaboration with the ONC's S&I program and used standards for patient consent as specified by the S & I Program. Used existing standards for patient choice, where applicable. Developed common way of describing patient choice that is machine readable and flexible. (e.g., integrating the Healthcare Enterprise (IHE) language for consent management, HITSP HL 7)	COTR reviews Machine Readable Text to ascertain that it is developed as specified in Task 10.0 above, provides feedback, accepts or rejects	Machine Readable Text includes COTR's feedback and submitted on time	Up to 5% of invoice #3
<b>C.3.11: Task 11. Deploy E-Consent Pilot</b>	Reviewed E-Consent Pilot with PO prior to deploying at existing active health	COTR monitors deployment to determine if pilot is	e-Consent Pilot is conducted and is in active	Up to 5% of invoice #4

Required Tasks	Task Standard	Method of Surveillance	Standard to be Met	Deduction
	site; Pilot is conducted with approved active health care partner site for 3-6 months	conducted and deployed as required	health information exchange environment on time	
<b>C.3.12: Task 12. Evaluate Patient Understanding &amp; Satisfaction</b>	Evaluated patient understanding of patient choice, sharing electronic health information in a clinical setting, and patient satisfaction	COTR monitors evaluation to determine if it is conducted as specified and required	Evaluation of Patient Understanding and Satisfaction regarding meaningful, informed patient choice, based on key elements, is conducted	Up to 5% of invoice #5
<b>C.3.13: Task 13. Provide and Present Written E-Consent Project Report</b>	Report summarizes the process, accomplishments, and results of the e-consent project, includes key findings, lessons learned, recommendations for operationalizing patient choice in electronic exchange of health information and meets the other requirements in Task 13.0 above.	COTR reviews Report outline and Report, provides feedback, and accepts or rejects	Final Report conforms to approved structure, summarizes process, accomplishments, and results of the e-consent project, includes key findings, lessons learned, recommendations and PO's feedback, is suitable for publication and is submitted on time	Up to 5% of invoice #5
<b>C.3.14: Task 14. Conduct Regular Status Meetings with ONC</b>	Regular status meetings scheduled and conducted	PO reviews agendas, status update report, and meeting minutes	Status meetings include review of work progress, specific deliverables, and future plans under the project	Up to 1% of invoice #5

Required Tasks	Task Standard	Method of Surveillance	Standard to be Met	Deduction
<b>C.3.15: Task 15. Monthly Progress Report</b>	Report describes progress against approved milestones and identifies project issues, barriers, and solutions. The Report is submitted at the same time as the monthly financial report and activities are aligned with the costs on the monthly financials	PO reviews Report, provides feedback, and accepts or rejects	Report includes PO's feedback is comprehensive, accurate, easy to follow, meets all criteria specified in Task 15.0 and is submitted on time	Up to 1% of invoice #5
<b>C.3.16: Task 16. Monthly Financial Report/Labor Matrix and Monthly Work Plan</b>	Report includes actual costs for reporting period, contract year-to-date, and cumulative costs to date, budgets costs for the reporting period, contract to date based on work performed, estimated costs by month for the remainder of the contract performance period, broken down by tasks, and subtasks, as appropriate	PO reviews Report, provides feedback, and accepts or rejects	Report includes COTR's feedback is comprehensive, accurate, easy to follow, meets all criteria specified in Task 15.0 and is submitted on time	Up to 1% of invoice #5

**FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)**

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

<https://www.acquisition.gov/far/index.html>

CLAUSE	TITLE	DATE
52.242-15	Stop-Work Order	August 1989
52.242-17	Government Delay of Work	April 1984

**SECTION G - CONTRACT ADMINISTRATION DATA**

**G.1 AUTHORITIES OF GOVERNMENT PERSONNEL**

Notwithstanding the Contractor's responsibility for total management during the performance of this contract, the administration of the contract will require maximum coordination between the Government and the Contractor. The following individuals will be the Government's points of contact during the performance of this contract.

**1. Contracting Officer**

The PSC Contracting Officer is the only individual authorized to modify this contract. The Contracting Officer responsible for administrative and contractual issues concerning this contract is:

Anthony Foster  
Program Support Center, Division of Acquisition Management  
5600 Fishers Lane, Room 5-101 Parklawn  
Rockville, Maryland 20857  
Phone: (301) 443-2475  
Fax: (301) 443-3849  
Email: Anthony.Foster@psc.hhs.gov

**2. Contracting Officer's Technical Representative (COTR) –**

Kathryn Marchesini  
HHS/OS/ONC  
200 Independence Ave. SW  
Room 745G.6  
Washington, DC 20201  
Ph: 202-205-3628  
Email: [Kathryn.Marchesini@hhs.gov](mailto:Kathryn.Marchesini@hhs.gov)

**3 Technical Monitoring**

(a) Performance of work under this contract must be subject to the technical direction of the Contracting Officers' Technical Representative identified above, or a representative designated in writing. The term "technical direction" includes, without limitation, direction to the contractor that directs or redirects the labor effort, shifts the work between work areas or locations, fills in details and otherwise serves to ensure that tasks outlined in the work statement are accomplished satisfactorily.

(b) Technical direction must be within the scope of the specification(s)/work statement.

The Contracting Officers' Technical Representative does not have authority to issue technical direction that:

- (1) Constitutes a change of assignment or additional work outside the specification(s)/statement of work;
  - (2) Constitutes a change as defined in the clause entitled "Changes";
  - (3) In any manner causes an increase or decrease in the contract price, or the time required for contract performance;
  - (4) Changes any of the terms, conditions, or specification(s)/work statement of the contract;
  - (5) Interferes with the contractor's right to perform under the terms and conditions of the contract;  
or
  - (6) Directs, supervises or otherwise controls the actions of the contractor's employees.
- (c) Technical direction may be oral or in writing. The Contracting Officers' Technical Representative shall confirm oral direction in writing within five work days, with a copy to the Contracting Officer.
- (d) The contractor shall proceed promptly with performance resulting from the technical direction issued by the Contracting Officers' Technical Representative. If, in the opinion of the contractor, any direction of the Contracting Officers' Technical Representative, or his/her designee, falls within the limitations in (b), above, the contractor shall immediately notify the Contracting Officer no later than the beginning of the next Government work day.
- (e) Failure of the contractor and the Contracting Officer to agree that technical direction is within the scope of the contract shall be subject to the terms of the clause entitled "Disputes."

G.2 INVOICE SUBMISSION:

The Contractor shall submit one original invoice including all required supporting documentation in accordance with the payment schedule in **Section B.2** to the below address and the COTR:

Division of Acquisition management/Program Support Center  
Attention: Anthony Foster, Contract Specialist  
Parklawn Building, Room 5-101

**Contract No. HHSP23320110023WC**

E-Consent Trial: Education, Collection, &  
Evaluation of Patient Choice in the Electronic  
Exchange of Health Information

5600 Fishers Lane  
Rockville, Maryland 20857  
Contract Number: HHSP23320110023WC

One (1) complete copy of each invoice including one (1) copy backup documentation shall be emailed to the COTR at [Kathryn.Marchesini@hhs.gov](mailto:Kathryn.Marchesini@hhs.gov).

The Contractor shall submit one (1) copy of the invoice including (1) copy of supporting documentation on a monthly basis, to the Finance Office for payment or an electronic copy of all invoices with all supporting documentation may be e-mailed to [PSC\\_invoices@psc.hhs.gov](mailto:PSC_invoices@psc.hhs.gov).

It is the responsibility of the Contractor to verify that the Finance Office has received their invoice. Calls concerning contract payment shall be directed to the general help-line number on (301) 443-3-6766.

The Contractor agrees to include the following information on its invoice:

- a. Contractor's name, address and invoice date;
- b. Contract number;
- c. Description, price, and quantity of property or services actually delivered or rendered;
- d. Period of performance for which costs are claimed;
- e. Shipping and payment terms;
- f. Other substantiating documentation or information as required by the contract;
- g. Name (where practicable), title, telephone number, and complete mailing address or responsible official to whom payment is to be sent;
- h. The Internal Revenue Service TAX IDENTIFICATION NUMBER or social security number;
- i. Signature of an authorized official certifying the invoice to be correct and proper for payment; and
- j. The COTR's name and telephone number on the face page.

In consideration of satisfactory performance of the work as described throughout this order, the Government will pay the Contractor the price as shown on the price sheet. This amount will be payable upon presentation of a proper invoice and upon receipt and acceptance by the Government of the services specified in the Schedule. It is the requirement of the Government to obtain complete and satisfactory performance in accordance with the terms of the specifications and quality standards of this contract. The Government is contracting for satisfactory performance of all work identified in the specifications, and deductions will, therefore, be made for any service not provided. The Government will determine monetary deductions for nonperformance of work under this contract, or for deficiencies in the performance of work and supplements "Termination for Cause."

It is agreed that failure to: accomplish any work required under this contract; to

satisfactorily accomplish such work; or to comply with any provisions of this contract, where due to the carelessness, neglect, or fault of the contractor, shall constitute a deficiency for which a reduction of payment will be made in accordance with the provisions of this contract.

**G.3 ELECTRONIC TRANSFER OF FUNDS PAYMENT**

Pursuant to FAR 52.232-33, Payment of Electronic Funds Transfer – Central Contractor Registration (OCT 2003), The Contractor shall designate a financial institute for receipt of electronic funds transfer payment. The designation shall be submitted in writing to the finance office at the following address payments under this contract shall be made by electronic funds transfer (EFT). The designation shall be submitted in writing to the finance office at the following address:

Program Support Center, Financial Management Services  
Parklawn Building, Room 16A-12  
5600 Fishers Lane  
Rockville, Maryland 20857

**G.4 PAYMENT BY ELECTRONIC FUNDS TRANSFER**

Pursuant to FAR 52.232-33, Payment by Electronic Funds Transfer –Central Contractor Registration, payments under this contract shall be made by electronic funds transfer. The Contractor shall register in the Central Contractor Registration database.

**G.5 KEY PERSONNEL (HHSAR 352.242-70, JANUARY 2006)**

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government.

The following individuals shall be considered key:

**G.6 SERVICE CONTRACT ACT**

The Service Contract Act of 1965 applies to this contract. Contractors performing on service contracts in excess of \$2,500 to which no predecessor contractor's collective bargaining agreement applies shall pay their employees at least the wages and fringe benefits found by the Department of Labor to prevail in the locality or, in the absence of a wage determination, the minimum wage set forth in the Fair Labor Standards Act. The Department of Labor Wage Determination listed below is incorporated in the solicitation and any subsequent revisions, effective at the date of contract award and can be assessed

electronically at <http://www.wdol.gov>

Wage Determination No. 05-2103 (Rev.-11) dated 6/17/2011  
States: District of Columbia, Maryland, Virginia

Contractor is put on notice that after performance begins, the Contractor is responsible for paying employees at least the applicable wage determination rate, if one exists, for the place of performance. The Department of Labor strictly enforces the Service Contract Act (SCA) for all service employees covered by SCA.

**G.7 EQUIPMENT**

No equipment shall be purchased under this contract by the Contractor without prior written authorization from the Contracting Officer.

**G.8 TRAVEL COSTS: if applicable.**

The Contractor will be reimbursed, not to exceed the amounts stated below, for all domestic travel as described below, incurred directly and specifically in the performance of this contract, claimed by the Contractor and accepted by the Contracting Officer.

NTE - \$36,100.00

- A. Airfare costs in excess of the lowest customary standard, coach, or equivalent airfare offered during normal business hours are unallowable except when such accommodations require circuitous routing, require travel during unreasonable hours, excessively prolong travel, result in increased costs that would offset transportation savings, are not reasonably adequate for the physical or medical needs of the traveler, or are not reasonably available to meet mission requirements. However, in order for airfare costs in excess of the above standard airfare to be allowable, the applicable condition(s) set forth must be documented and justified.
- B. Costs of rail travel by most direct route, first-class with lower berth or nearest equivalent.
- C. Travel by motor vehicle shall be reimbursed on a reasonable actual expense basis, or at the Contractor's option, on a mileage basis at the current Federal Travel Regulation rate, plus any toll or ferry charges.
- D. Reasonable subsistence not in excess of actual itemized expenses not to exceed the ceilings in the Federal Travel Regulations in effect at the time of incurred cost.

The contractor's reimbursement is limited by regulations of the General Services Administration (GSA) as applied to Civil Service employee travel. Costs for transportation, lodging, meals, and incidental expenses incurred by contractor personnel on official company business are allowable subject to the limitations contained in FAR 31.205-46 Travel Costs.

The following summarizes some of the basic travel reimbursement policies:

1. Travel by air authorized for coach only. Travel by train and bus authorized for up to first class. Contractor is expected to plan sufficiently to take advantage of discount fares  
<http://apps.fas.gsa.gov/citypairs/search/index.cfm?ft;>
2. Local transportation including transportation to and from airports, bus terminals, and railway stations;
3. Private auto at current GSA rates when private auto travel combined with per diem is less than the cost by common carrier including per diem  
[http://www.gsa.gov/Portal/gsa/ep/contentView.do?contentType=GSA\\_BASIC&contentId=17943](http://www.gsa.gov/Portal/gsa/ep/contentView.do?contentType=GSA_BASIC&contentId=17943)
4. Parking/tolls for automobile travel;
5. Rental car, not to exceed compact vehicle, when approved in advance by the COTR;
6. Per Diem at rates established by the GSA.

Travel claims shall be submitted and included on monthly invoices for approval. Listed below is a description of receipts required as attachments to the invoice to support travel claims:

1. Copy of common carrier ticket reflecting class of travel, dates of travel and amount of fare;
2. Lodging receipt;
3. Parking/tolls receipt;
4. Rental car receipt including receipts for gasoline;
5. Receipts for taxi travel.

When the contractor is requested by the COTR to travel outside the contractor's normal commuting area to deliver services, the contractor will be entitled to their normal hourly payment for the time that they are in transit. Such in transit time shall be determined by the usual and customary time for travel between the respective points when considering both the cost and time required for the mode of travel. For example, if the contractor has to travel to San Francisco for a project then they will get paid at their normal hourly rate for their hours of traveling. Total travel expenses will not exceed the amount specified in this contract without prior written consent of the Contracting Officer.

Domestic travel expenses incurred by the Contractor in direct performance of this requirement shall be reimbursed provided such travel is necessary for the performance of this requirement and the cost does not exceed: the lowest customary standard, coach, or equivalent airfare offered during normal business hours for air travel. Other Direct Costs (ODC) shall be negotiated for each requirement and all invoices shall be supported by receipts.

**G.9 GOVERNMENT FURNISHED INFORMATION:**

- [http://healthit.hhs.gov/portal/server.pt/community/healthit\\_hhs\\_gov\\_privacy\\_and\\_security/1147](http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_privacy_and_security/1147)
- [http://healthit.hhs.gov/portal/server.pt/document/947492/tigerteamrecommendationletter8-17\\_2\\_pdf](http://healthit.hhs.gov/portal/server.pt/document/947492/tigerteamrecommendationletter8-17_2_pdf)
- [http://www.healthit.hhs.gov/portal/server.pt/gateway/PTARGS\\_0\\_10779\\_891071\\_0\\_0\\_18/20091005\\_Consumer%20Preferences\\_Draft\\_Requirements\\_Document.pdf](http://www.healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10779_891071_0_0_18/20091005_Consumer%20Preferences_Draft_Requirements_Document.pdf)
- <http://www.health.gov/communication/literacy/quickguide/default.htm>
- <http://www.access-board.gov>
- <http://www.acquisition.gov>

**Contract No. HHSP23320110023WC**

E-Consent Trial: Education, Collection, &  
Evaluation of Patient Choice in the Electronic  
Exchange of Health Information

- <http://www.section508.gov>
- <http://www.hhs.gov/web/policies/index.html>

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

### **H.1 REQUIREMENTS CONCERNING DATA, DATA RIGHTS AND COMPUTER SOFTWARE**

Notwithstanding any other clause concerning data, data right and computer software and hardware under this contract, all data and source code produced, recorded, transferred manipulated under this contract shall remain the exclusive property of the Government. Irrespective of the manner or method of recording or storage and no matter what form of computer mechanism is used in the processing of said information of data. The Government shall retain exclusive right and domain over any product produced under this contract or any other use of the data produced under this contract by either plan or accident.

### **H.2 CONTRACTOR PERFORMANCE EVALUATION REPORT**

During the life of this contract, Contractor performance will be evaluated on an initial and final reporting frequency pursuant to FAR Subpart 42.1502 & 1503 using the Contractor Performance Assessment Reporting System <https://www.cpars.csd.disa.mil>. This evaluation shall become a part of the contract file and shall be used as past performance information in evaluating the Contractor's and significant subcontractors' or affiliates' past performance on future contracts.

### **H.3 PERFORMANCE BASED SERVICES**

Deliverables shall comply with the minimum requirements described herein. The service and deliverable content format and due date requirements in the SOW are considered minimum performance standards the Contractor must meet or exceed. Failure to achieve these standards will be communicated in writing to the Contractor promptly upon receipt of the deliverable. Any needed revisions identified by the COTR will be accomplished by the Contractor at no increase in the fixed price of the contract. The Contracting Officer may withhold payment of the Contractor's invoice(s) for incomplete or inadequate work products. Final payment will not be made until all services and work products called for under the contract have been delivered/performed by the Contractor and accepted by the COTR.

H.4 HHSAR 352.242-70 – KEY PERSONNEL (JAN 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

The following individuals shall be considered key:

Name

Title

*Clifford Otte*

*Project Leader/Director*

*Herbert J. Glose*

*Legal Expert*

*David McNully*

*Technical Visual Commutations/Design Expert*

*Mark Hochauser*

*Consumer Literacy/Education Expert*

*Katherine Cauley, PhD*

*Consume/Evaluations/Survey Expert*

| PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

I.1 FAR 52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (FEB 1998) & FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE. (FEB 1998)

This contract incorporates some FAR provisions/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): FAR Clauses <http://www.arnet.gov/far/index.html> and HHSAR Clauses <http://edocket.access.gpo.gov/2009/E9-26948.htm> The applicable provisions/clauses are as follows:

FEDERAL ACQUISITION REGULATIONS (FAR) 48 (CFR CHAPTER 1) CONTRACT CLAUSES

<u>FAR Clause No.</u>	<u>Title and Date</u>
52.202-1	Definitions. (APR 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. (OCT 2010)
52.203-8	Cancellation, Rescission, and Recovery of Funds_for Illegal or Improper Activity. (JAN 1997)
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity. (JAN 1997)
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (OCT 2010)
52.203-13	Contractor Code of Business Ethics and Conduct (APR 2010)
52-203-14	Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009 (DEC 2007)
52.204-4	Printed or Copied Double-Sided on Recycled Paper (MAY 2011)
52.204-7	Central Contractor Registration. (APR 2008)
52.204-10	Reporting Executive Compensation and First-Tier Subcontractor Awards (JUL 2010)
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (DEC 2010)
52.215-2	Audit and Records - Negotiation. (JUN 1999)
52.215-8	Order of Precedence - Uniform Contract Format. (OCT 1997)
52.227-14	Rights in Data-General (DEC 2007)
52.227-17	Rights in Data-Special Works (DEC 2007)
52-219-1	Small Business Program Representation (APR 2011)
52.219-8	Utilization of Small Business Concerns. (JAN 2011)
52.219-14	Limitations on Subcontracting (DEC 1996)

52-219-28	Post-Award Small Business Program Representation (APR 2009)
52.222-3	Convict Labor. (JUN 2003)
52.222-26	Equal Opportunity. (MAR 2007)
52.222-35	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans. (SEP 2006)
52.222-36	Affirmative Action for Workers with Disabilities. (OCT 2010)
52.222-37	Employment Reports Veterans (SEP 2010)
52.222-41	Service Contract Act of 1965. (NOV 2007)
52.223-6	Drug-Free Workplace. (MAY 2001)
52.227-3	Patent Indemnity (APR 1984)
52-227-15	Rights in Data – General (DEC 2007)
52.232-1	Payments (APR 1984)
52.232-8	Discounts for Prompt Payment. (FEB 2002)
52.232-9	Limitation on Withholding of Payments. (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)
52.232-34	Payment by Electronic Funds Transfer - Other than Central Contractor Registration. (MAY 1999)
52.233-1	Disputes. (JUL 2002)
52.233-3	Protest after Award. (AUG 1996) Alternate I (JUN 1985)
52.233-4	Applicable Law for Breach of Contract Claim (OCT 2004)
52.239-1	Privacy or Security Safeguards (AUG 1996)
52.242-13	Bankruptcy. (JUL 1995)
52.242-15	Stop-Work Order. (AUG 1989)
52.243-1	Changes –Fixed-Price (AUG 1987) ALT I (APR 1984)
52.246-20	Warranty of Services. (MAY 2001)
52.249-2	Termination for Convenience of the Government (Fixed-Price) (MAY 2004)
52.249-8	Default (Fixed-Price Supply and Service). (APR 1984)
52.249-14	Excusable Delays. (APR 1984)
52.253-1	Computer Generated Forms. (JAN 1991)

I.1 FAR 52.215-19 NOTIFICATION OF OWNERSHIP CHANGES. (OCT 1997)

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

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

(2) The Contractor shall also notify the ACO within 30 days whenever changes to asset

valuations or any other cost changes have occurred or are certain to occur as a result of a change in ownership.

(b) The Contractor shall -

- (1) Maintain current, accurate, and complete inventory records of assets and their costs;
- (2) Provide the ACO or designated representative ready access to the records upon request;
- (3) Ensure that all individual and grouped assets, their capitalized values, accumulated depreciation or amortization, and remaining useful lives are identified accurately before and after each of the Contractor's ownership changes; and
- (4) Retain and continue to maintain depreciation and amortization schedules based on the asset records maintained before each Contractor ownership change.

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

- (1) The designated payment office will make interim payments for contract financing on the 30th day after the designated billing office receives a proper payment request.

I.2 52.217-9 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 60 days.

I.3 52.219-6 NOTICE OF TOTAL SMALL BUSINESS SET-ASIDE. (JUN 2003)

(a) *Definition*. "Small business concern," as used in this clause, means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the size standards in this solicitation.

(b) General.

(1) Offers are solicited only from small business concerns. Offers received from concerns that are not small business concerns shall be considered nonresponsive and will be rejected.

(2) Any award resulting from this solicitation will be made to a small business concern.

(c) *Agreement*. A small business concern submitting an offer in its own name shall furnish, in performing the contract, only end items manufactured or produced by small business concerns in the

United States or its outlying areas. If this procurement is processed under simplified acquisition procedures and the total amount of this contract does not exceed \$25,000, a small business concern may furnish the product of any domestic firm. This paragraph does not apply to construction or service contracts.

I.4 52.227-17 RIGHTS IN DATA—SPECIAL WORKS. (Dec 2007)

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

“Data” means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

“Unlimited rights” means the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

(b) Allocation of Rights.

(1) The Government shall have—

(i) Unlimited rights in all data delivered under this contract, and in all data first produced in the performance of this contract, except as provided in paragraph (c) of this clause.

(ii) The right to limit assertion of copyright in data first produced in the performance of this contract, and to obtain assignment of copyright in that data, in accordance with paragraph (c)(1) of this clause.

(iii) The right to limit the release and use of certain data in accordance with paragraph (d) of this clause.

(2) The Contractor shall have, to the extent permission is granted in accordance with paragraph (c)(1) of this clause, the right to assert claim to copyright subsisting in data first produced in the performance of this contract.

(c) Copyright—

(1) Data first produced in the performance of this contract.

(i) The Contractor shall not assert or authorize others to assert any claim to copyright subsisting in any data first produced in the performance of this contract without prior written permission of the Contracting Officer. When copyright is asserted, the Contractor shall affix the appropriate copyright notice of 17 U.S.C. 401 or 402 and acknowledgment of Government sponsorship (including contract number) to the data when delivered to the Government, as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office. The Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all delivered data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government.

(ii) If the Government desires to obtain copyright in data first produced in the performance of this contract and permission has not been granted as set forth in paragraph (c)(1)(i) of this clause, the

Contracting Officer shall direct the Contractor to assign (with or without registration), or obtain the assignment of, the copyright to the Government or its designated assignee.

(2) *Data not first produced in the performance of this contract.* The Contractor shall not, without prior written permission of the Contracting Officer, incorporate in data delivered under this contract any data not first produced in the performance of this contract and that contain the copyright notice of [17 U.S.C. 401 or 402](#), unless the Contractor identifies such data and grants to the Government, or acquires on its behalf, a license of the same scope as set forth in paragraph (c)(1) of this clause.

(d) *Release and use restrictions.* Except as otherwise specifically provided for in this contract, the Contractor shall not use, release, reproduce, distribute, or publish any data first produced in the performance of this contract, nor authorize others to do so, without written permission of the Contracting Officer.

(e) *Indemnity.* The Contractor shall indemnify the Government and its officers, agents, and employees acting for the Government against any liability, including costs and expenses, incurred as the result of the violation of trade secrets, copyrights, or right of privacy or publicity, arising out of the creation, delivery, publication, or use of any data furnished under this contract; or any libelous or other unlawful matter contained in such data. The provisions of this paragraph do not apply unless the Government provides notice to the Contractor as soon as practicable of any claim or suit, affords the Contractor an opportunity under applicable laws, rules, or regulations to participate in the defense of the claim or suit, and obtains the Contractor's consent to the settlement of any claim or suit other than as required by final decree of a court of competent jurisdiction; and these provisions do not apply to material furnished to the Contractor by the Government and incorporated in data to which this clause applies.

I.5 DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION  
REGULATION (HHSAR) (49 CFR CHAPTER 3) CLAUSES

<u>HHSAR Cause No.</u>	<u>Title and Date</u>
352.202-1	Definitions. (JAN 2006)
352.224-70	Privacy Act. (JAN 2006)
352.203-70	Anti-Lobbying (JAN 2006)
352-222-70	Contractor Cooperation in Equal Employment Opportunity (OCT 2009)
352.239-72	Security Requirements for Fed. Information Technology Resources (October 2009)