



**PERFORMANCE WORK STATEMENT (PWS)**

**DEPARTMENT OF VETERANS AFFAIRS**

**Office of Health Informatics (OHI)**

**Clinical Informatics and Data Management Office (CIDMO)**

**Human Factors Engineering (HFE)**

**Human Factors Services (HFS)**

**Indefinite Delivery, Indefinite Quantity (IDIQ)**

# Contents

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## Table of Contents

PERFORMANCE WORK STATEMENT (PWS) .....	1
1.0 BACKGROUND .....	3
2.0 APPLICABLE DOCUMENTS .....	4
3.0 SCOPE OF WORK .....	5
3.1 ORDER TYPE .....	6
4.0 PERFORMANCE DETAILS .....	6
4.1 PERFORMANCE PERIOD .....	6
4.2 PLACE OF PERFORMANCE .....	6
4.3 TRAVEL OR SPECIAL REQUIREMENTS .....	6
4.4 GOVERNMENT FURNISHED PROPERTY .....	7
4.5 SECURITY AND PRIVACY .....	8
4.5.1 POSITION SENSITIVITY .....	8
5.0 SPECIFIC TASKS AND DELIVERABLES .....	9
5.1 PROJECT MANAGEMENT .....	15
5.1.1 CONTRACTOR PROJECT MANAGEMENT PLAN .....	15
5.1.2 REPORTING REQUIREMENTS .....	16
5.1.3 TECHNICAL KICKOFF MEETING .....	17
5.2 HUMAN FACTORS ENGINEERING SERVICES .....	17
5.2.1 SPECIFYING HIS CONTEXT OF USE AND USER REQUIREMENTS .....	20
5.2.2 DESIGNING HIS SOLUTIONS .....	22
5.2.3 EVALUATING HIS USABILITY .....	25
5.3 COORDINATING ENGAGEMENTS, PROJECTS, AND STUDIES .....	28
5.4 MATURING CONTENT FOR THE USER EXPERIENCE (UX) GUIDE .....	32
<b>Rights in Deliverables</b> .....	33
6.0 GENERAL REQUIREMENTS .....	34
6.1 PERFORMANCE METRICS .....	34
6.2 SECTION 508 – ELECTRONIC AND INFORMATION TECHNOLOGY (EIT) STANDARDS .....	35
6.2.1 EQUIVALENT FACILITATION .....	35
6.2.2 COMPATIBILITY WITH ASSISTIVE TECHNOLOGY .....	36
6.3 ENTERPRISE AND IT FRAMEWORK .....	36
6.4 INFORMATION TECHNOLOGY USING ENERGY-EFFICIENT PRODUCTS .....	37
ADDENDUM A – General Notes .....	38
B2. ACCESS TO VA INFORMATION AND VA INFORMATION SYSTEMS .....	38
B3. VA INFORMATION CUSTODIAL LANGUAGE .....	38
B4. INFORMATION SYSTEM DESIGN AND DEVELOPMENT .....	39
B5. INFORMATION SYSTEM HOSTING, OPERATION, MAINTENANCE, OR USE .....	39
B6. SECURITY INCIDENT INVESTIGATION .....	39
B7. LIQUIDATED DAMAGES FOR DATA BREACH .....	39
B8. SECURITY CONTROLS COMPLIANCE TESTING .....	39

## 1.0 BACKGROUND

The Office of Health Informatics (OHI) is integral to Veterans Health Administration (VHA) programs that provide patient-centered health care to Veterans, offering advanced and secure enterprise data systems, sophisticated analytic and measurement solutions, decision support, business intelligence and web communications. OHI facilitates evidence-based decisions for individual Veterans and their families, patient populations, clinicians, and those managing health care delivery systems. The Human Factors Engineering (HFE) directorate exists within Department of Veterans Affairs (VA), VHA, Office of Health Informatics (OHI), Clinical Informatics and Data Management Office (CIDMO). HFE seeks to increase awareness and application of human factors principles, improving performance and safety of VA health information systems (HIS) by optimizing the end-user experience. HFE offers human-centered design (HCD) services (including user interface design and usability assessments) for a variety of VA-developed and acquired products and services. HFE requires engineering support for numerous projects that range from understanding user needs through implementation, amongst a diverse population of Veteran, Caregiver, Administrative and Clinician Users to ensure that the health information technology (HIT) provided for their use is helpful and relevant to them. A best practice in HCD is to encourage end-user feedback at all stages of the development lifecycle.

Beyond the name of the HFE organization, 'human factors engineering' is the *scientific discipline* concerned with the understanding of interactions among humans and other elements of a system, and the *engineering profession* that applies theory, principles, data and methods to design in order to optimize human well-being and overall *system* performance (International Ergonomics Association). A 'system' is a network or group of interdependent components and operational processes that work together to accomplish the objectives and requirements (Design for Safety).

The VHA requires a rigorous human factors engineering approach in operational settings to ensure that all HIT (acquired or developed) and corresponding elements of the health care socio-technical system are jointly optimized to provide a user experience with high performance and satisfaction. The HFE office optimizes both employee (i.e., clinicians) and Veteran user experience with HIT, medical devices and consumer products (e.g., tablets, smartphones, wearables) via an iterative HCD approach offered in the International Organization for Standardization (ISO) 9241: plan the process, understand context of use, specify requirements, design, and test user interfaces to ensure they improve user effectiveness, minimize mental workload, support decision making, maximize clinical workflow efficiency, reduce human error, improve patient safety, and enhance quality of care.

The HFE office responds to requests for collaboration and partnership from multiple channels (e.g., VA/VHA Initiatives, National Program office objectives, field inquiries,

system platform sponsors) for human factors engineering services in support of analysis of user needs, (human-centered) design, re-design, and usability testing. Depending on objectives, these services may be provided for a particular activity, intermittently, or in concert over an extended period of time. While all work undertaken applies human factors methods and techniques, projects vary significantly in terms of the role of end users, the number and type of HIT systems included, and the level of effort required to complete. For example, projects range from a heuristic evaluation of a mobile app performed by human factors experts only, to a rapid ethnography study to understand and document clinical workflows that may require observing and interviewing dozens of clinical staff members.

Certain engagements are continually supported (e.g., legacy systems such as Veteran's Health Information Systems and Technology Architecture (VistA) / Computerized Patient Record System (CPRS), VA's in-house developed electronic health record (EHR)), while other needs will emerge throughout the Period of Performance (PoP). Examples of ad hoc support provided in recent months include end user testing of a Comprehensive Suicide Risk Assessment template (clinical documentation tool) and its use in the context of EHR clinical workflow and evaluation of a web-based dashboard (decision support tool) used by Veteran Crisis Line staff.

## **2.0 APPLICABLE DOCUMENTS**

The Contractor shall follow guidance in the following documents, in the performance of this effort:

- A. ISO Standard: Ergonomics of human-system interaction -- Usability: Definitions and concepts (ISO 9241-11:2018)
- B. ISO Standard: Human-centered design processes for interactive systems (ISO 9241-210:2009)
- C. ISO Standard: Ergonomics of human-system interaction -- Usability methods supporting human-centred design (ISO/TR 16982:2002)
- D. ISO Standard: Ergonomics — General approach, principles and concepts (ISO 26800:2011)
- E. ISO Standard: Ergonomics of human-system interaction—Principles for the presentation of information (ISO 9241-112:2017)
- F. ISO Standard: Ergonomics of human-system interaction—Dialogue principles (ISO 9241-110:2008)
- G. ISO Standard: Ergonomics of human-system interaction— Guidance on visual user-interface elements (ISO 9241-161:2016)
- H. ISO Standard: Ergonomics of human-system interaction— Ergonomic principles for the design and evaluation of environments of interactive systems (ISO 9241-500:2018)
- I. ISO Standard: Ergonomics principles in the design of work systems (ISO 6385:2016)

- J. ISO Standard: Ergonomics of human-system interaction— Forms (ISO 9241-143:2012)
- K. International Electrotechnical Commission (IEC) Medical device software — Software life cycle processes (IEC 62304:2006)
- L. ISO/IEC Standard: Systems and software engineering -- Software product Quality Requirements and Evaluation (SQuaRE) -- Common Industry Format (CIF) for usability: User needs report (ISO/IEC 25064:2013)
- M. ISO/IEC Standard: Systems and software engineering -- Systems and SQuaRE – CIF for usability: Context of use description (ISO/IEC 25063:2014)
- N. National Institute of Standards and Technology (NIST) Interagency/Internal Report (NISTIR) 7742: Customized Common Industry Format Template for Electronic Health Record Usability Testing
- O. Office of the National Coordinator Health Information Technology (ONC) 2015 Edition of Safety-enhanced Design ([URL](#))

### 3.0 SCOPE OF WORK



The purpose of this contract is to obtain human factors engineering support services for the HFE office. The Contractor shall provide human factors engineering support from knowledgeable resources with appropriate training, education, expertise and credentials to conduct the studies in accordance with HFE and VA policies and procedures. The Contractor shall develop, submit, and execute scientifically valid studies that include objectives, background, methodology, data analysis and results discussion that is consistent with the nature of the study. While occasional organizational changes may occur, the scope of this effort is intended to include projects and programs listed below as well as new ones that may emerge:

1. **Legacy VistA/CPRS:** VA's current electronic health record (EHR) system. Includes the Joint Legacy Viewer (JLV) and CPRS support on national releases.
2. **Electronic Health Record Modernization (EHRM):** a new electronic health record system that will facilitate interoperability with the Department of Defense (DoD) and other health care partners to enhance patient-centered, team-based and evidence-based care by giving health care providers a complete picture of a patient's care and treatment history.
3. **Connected Care:** tools for Veterans, family caregivers, and clinicians provided through a number of modalities including smartphones, tablets, kiosks and websites. My HealtheVet, Web and Mobile Solutions, and Telehealth are part of this suite.
4. **Community Care:** refers eligible Veterans for care in the community, collecting data about the care provided and patient outcomes achieved, and paying for the care.
5. **VA Innovation Office:** identifies and funds innovations that show promise for improving care and benefits delivery and Veteran and VA staff experiences.

6. **Clinical Informatics and Data Management Office (CIDMO):** entities such as Veterans Health Information Exchange, Knowledge-Based Systems, Informatics Patient Safety and Bar Code Medication Administration that periodically request services from HFE.
7. **Other VA administrations and program offices:** HFE conducts *ad hoc* reviews of websites, commercial software products and a variety of other systems, including support for Veteran Benefits Administration (VBA), Office of Information and Technology (OI&T/OIT), Veterans Experience Office (VEO) and Digital Service at VA (DSVA).

**VA VISN and Field Offices:** VISN and Field offices develop and deploy solutions for local or VISN-wide use and occasionally request HFE consultation and/or review.

The Contractor may be required to provide a range of services from an isolated activity (for example, planning and executing a standalone performance-based usability test) to a collection of services (for example, conducting a user needs assessment that leads to iterations of User Interface (UI) designs that then undergo usability testing). HFE responds to numerous project and programs' requests for Human Factors Services within VA and VHA, and the variability of the needs change from each activity based on the agreed upon study objectives. The Contractor shall provide the following human factors engineering services, outlined in the below PWS sections:

### 3.1 ORDER TYPE

This is a Multiple Award Indefinite Delivery/Indefinite Quantity (IDIQ) contract. The task orders will be awarded on a Fixed-Firm Price (FFP) basis except for travel which shall be on Reimbursable basis with a Not To Exceed (NTE) amount per Task Order (TO) under Time and Materials.

## 4.0 PERFORMANCE DETAILS

### 4.1 PERFORMANCE PERIOD

The Period of Performance (PoP) shall be an ordering period for up to five (5) years. The Period of Performance of the Task Orders shall be determined and defined at the Task Order level.

### 4.2 PLACE OF PERFORMANCE

Place of performance shall be identified in individual task orders, but it is anticipated that a majority of the efforts under this contract shall be performed at Contractor facilities. The Contractor shall identify the Contractor's place of performance in their Task Execution Plan (TEP) submission.

### 4.3 TRAVEL OR SPECIAL REQUIREMENTS

Travel shall be in accordance with individual task order requirements. The Government anticipates travel under this effort to perform the tasks associated with the effort, as well as to attend program-related meetings or conferences through the PoP. Travel shall be Reimbursable with an NTE ceiling on travel expenses per TO. Travel expenses shall be

invoiced and paid against the travel CLIN, which will have an NTE price specified on each TO.

Travel shall be in accordance with the Federal Travel Regulations (FTR) and requires advance concurrence by the Contracting Officer's Representative (COR). Each Contractor invoice must include copies of all receipts that support the travel costs claimed in the invoice. Contractor travel within the local commuting area will not be reimbursed. These costs will be considered to be reasonable and allowable only to the extent that they do not exceed the maximum per diem rates in effect at the time of travel as set forth in the FTR.

#### **4.4 GOVERNMENT FURNISHED PROPERTY**

Government Furnished Property may be provided and shall be identified in the individual task orders. The VA HFE office will provide access to the tools listed below. The number of Government-furnished licenses available for Contractor use is listed in parentheses. If the mandated toolset changes during the ordering period, then the Government will provide access to the new toolset.

- Balsamiq (1)
- Morae (2)
- Survey Monkey (1)
- PSPP (open source version of SPSS)

In addition to the licensed tools above, HFE also uses no-cost versions of web-based tools such as Trello and AirTable. Lync/Skype for Business is VA's official collaboration tool and is used extensively for VA-initiated meetings, and is available on the VA Network and shall be the primary teleconferencing tool used during performance of studies. The Contractor shall ensure contract staff have access and are knowledgeable with Microsoft (MS) Office based products (Word, Excel, PowerPoint, Project, Publisher, Access, etc.) and common Design, User Experience, Usability and User Interface tools (e.g., Adobe InDesign, Axure, SnagIt, OptimalSort, etc.).

The Government has determined that remote access solutions involving Citrix Access Gateways (CAG) have proven to be an unsatisfactory access method to complete some of the tasks required. The Government will evaluate the need for CAG on a case by case basis. The Government also understands that Government Furnished Equipment (GFE) is limited to Contractors that may require direct access to the network in order to ensure usability testing software compliance with VA network environments; upload/download/ manipulate content on SharePoint Server; and configure and assess secure applications, such as NATREM (NATional REMinder Test System) and CPRS. The usage of GFE will be on a case by case basis and must be approved by the COR when sufficient. Each instance where CAG is not sufficient shall be justified to the COR prior to issuing. Based on the Government assessment of remote access solutions and the requirements of this TO, the Government estimates that 'standard laptops' with charging cables will be required by this TO.

The Contractor is responsible for providing any other computer accessories (e.g., keyboards, mice, cables) as necessary and any VA installation required for accessories shall be coordinated with the COR. The Contractor shall document, track, and monitor all GFE, and any GFE can be audited by the COR or local VA resource. The Contractor shall ensure a current list of GFE to include the name, computer make and model, serial number, and previous PM/COR (if existing issued device is used) is provided to the COR and Contracting Officer.

Regardless of use of CAG or GFE, the Contractor shall be accessible on the VA Network account for communication purposes, including via Outlook and Skype/Lync, and for tool access (i.e., SharePoint, NATREM, etc.).

## 4.5 SECURITY AND PRIVACY

### 4.5.1 POSITION SENSITIVITY

<b>Position Sensitivity</b>	<b>Background Investigation</b> (in accordance with Department of Veterans Affairs 0710 Handbook, "Personnel Suitability and Security Program," Appendix A)
<b>Low / Tier 1</b>	<b>Tier 1 / National Agency Check with Written Inquiries (NACI)</b> A Tier 1/NACI is conducted by OPM and covers a 5-year period. It consists of a review of records contained in the OPM Security Investigations Index (SII) and the DOD Defense Central Investigations Index (DCII), FBI name check, FBI fingerprint check, and written inquiries to previous employers and references listed on the application for employment. In VA it is used for Non-sensitive or Low Risk positions.
<b>Moderate / Tier 2</b>	<b>Tier 2 / Moderate Background Investigation (MBI)</b> A Tier 2/MBI is conducted by OPM and covers a 5-year period. It consists of a review of National Agency Check (NAC) records [OPM Security Investigations Index (SII), DOD Defense Central Investigations Index (DCII), FBI name check, and a FBI fingerprint check], a credit report covering a period of 5 years, written inquiries to previous employers and references listed on the application for employment; an interview with the subject, law enforcement check; and a verification of the educational degree.
<b>High / Tier 4</b>	<b>Tier 4 / Background Investigation (BI)</b> A Tier 4/BI is conducted by OPM and covers a 10-year period. It consists of a review of National Agency Check (NAC) records [OPM Security Investigations Index (SII), DOD Defense Central Investigations Index (DCII), FBI name check, and a FBI fingerprint check report], a credit report covering a period of 10 years, written inquiries to previous employers and references listed on the application for

The position sensitivity and the level of background investigation commensurate with



the required level of access for the following tasks within the Performance Work Statement are:

	<b>Position Sensitivity and Background Investigation Requirements</b>		
<b><u>Task Number</u></b>	<b><u>Low/NACI</u></b>	<b><u>Moderate/MBI</u></b>	<b><u>High/BI</u></b>
5.1	<input checked="" type="checkbox"/>		
5.2	<input checked="" type="checkbox"/>		
5.3	<input checked="" type="checkbox"/>		
5.4	<input checked="" type="checkbox"/>		
5.5	<input checked="" type="checkbox"/>		
5.6	<input checked="" type="checkbox"/>		

The Tasks identified above and the resulting Position Sensitivity and Background Investigation requirements identify, in effect, the Background Investigation requirements for Contractor individuals, based upon the tasks the particular Contractor individual will be working. The submitted Contractor Staff Roster must indicate the required Background Investigation Level for each Contractor individual based upon the tasks the Contractor individual will be working, in accordance with their submitted proposal.

## 5.0 SPECIFIC TASKS AND DELIVERABLES

The Contractor shall follow, support, and endorse the application of HCD practices within HFE and VA. The Contractor shall support the usability, macro-ergonomics, human factors, cognitive engineering and interaction design functions in collaboration with HFE to perform studies for assessments, evaluations, and analyses to provide recommendations for interactive systems to improve their usefulness and usability. The Contractor shall provide use of a collaboration tool such as WebEx, during the PoP that is both compatible with Morae and can be used by clinician and Veteran participants both within and outside the VA firewall.

A 'Study' is the use of one or more methods to achieve an objective. Sample study methods include heuristic evaluations, focus groups, and performance-based usability test. The Contractor shall perform a mix of face-to-face and virtual methods to conduct studies. The Contractor shall align the proposed method to the agreed upon study objectives. Studies may contain 'Participants' or individuals representing an end user, as aligned with the executed method, and be performed over a series of 'Sessions'. A Session is a single event attended by one or more Participants. For example, a focus group could consist of a single session with 9 Participants, where a performance-based usability test could consist of 9 sessions with a single Participant in each. Each project may have one or more individual studies established to meet project objectives, and engagements may have one or more projects underway, prepped in the back log for future work, or previously completed. Individual projects have targeted completion dates, while engagements do not and represent the partnership to mature the HCD

approach throughout VA.

The Contractor shall be responsible for managing assigned projects and executing established processes to identify and plan effective and timely HCD activities across various engagements throughout the system development lifecycle. The Contractor shall support the continued provisioning of human factors services with HFE for external requests as well as for HFE-initiated studies. When HFE's work is performed for an external partner, they are identified as the Sponsor or the primary customer of HFE. The Contractor shall identify all key stakeholders for executed studies.

Tasks may require Access to local and national VHA Data, such as Protected Health Information, Sensitive Personal Information and Personally Identifiable Information, Individually Identifiable Information (PHI/SPI/PII/III) during the course of projects, for multiple purposes as an Administrative or Special User including but not limited to: quality assessment and improvement, operational reporting, compliance and oversight, and general administrative duties not generally associated with clinical care. The Contractor shall ensure all contractor-provided resources are covered under a Business Associate Agreement (BAA) as a covered entity.

The initiatives supported range in size and duration from a single assessment of a wireframe or prototype to an ongoing, long-term engagement providing human factors support for legacy VistA and CPRS workflows and improvements. While TO deliverables are expected to be actionable and highly operational in nature, some of them may also be synthesized with other data and used to inform strategic direction. HFE has a defined set of processes, methods (services) and reports across key areas of engagement and strives for continuous improvement. The Contractor shall execute human factors engineering activities in accordance with approved HFE office methods, processes, and report formats as documented in the HFE UX Guide and HFE Program SharePoint.

The Contractor's level of involvement on projects and studies shall vary, as the Contractor shall support the overall HFE team and complete portions of study activities in support of the overarching objectives. The Contractor shall provide a Study Lead and/or a Study Support role for individual studies as agreed upon with the Government HFE Lead. The Contractor shall collaborate with other HFE Resources on each assigned study activity, which may include Government staff, other contractors, and Intergovernmental Personal Assignment (IPA) staff.

The Contractor shall propose use of an industry standard, or minimally, a recommended approach supported by published evidence when an existing HFE process is not yet established. The Contractor shall perform study kick-off meetings to document the context of need for a study request for any assigned study activity, and load the document as a Working Product. From the study kick-off meeting and other related information, the Contractor shall propose to the HFE Government Lead a Functional Point Estimate (FPE) for the scope of each assigned task, while referencing the Government provided Nominal Descriptions to support the FPE. The Contractor shall confirm acceptance with the HFE Government Lead of the agreed-upon Functional Points in the Study Proposal review. The Contractor shall create and include a *proposal*

(concurrent on by the HFE Government Lead and sponsor before work can begin), a *study plan*, and the *study report* for each Study Package, each of which the Contractor shall upload to the HFE Effort Tracker SharePoint (VA Network URL provided upon award, referred to as Effort Tracker throughout) as created. The Effort Tracker is the single authoritative project and study repository. The Contractor shall perform and document White Glove (WG) reviews and formal Peer Reviews (PR) on assigned work activities, and submit as a Working Product to the relevant Effort Tracker entry. The Study Package shall be provided for task performed in PWS 5.2, 5.3, 5.4 and 5.5. For taskings focused on clinical process analysis and redesign, the deliverables will come in a Clinical Study Package, maintaining the same format but separated for fiscal tracking purposes.

The Study Proposal shall minimally include:

- 1) Introduction
  - a) Provide an overview of the study being proposed. Be sure to include the intent of the study.
- 2) Objectives
  - a) Describe the purpose of the study
  - b) Mention what is not in scope or evaluated
- 3) Study Design
  - a) Include the study method used
  - b) If possible, provide a link to the method details
  - c) Provide a brief description of the test data being used, test measures, and study participants
  - d) Describe the high level expected results of the study
- 4) Schedule (High Level)
  - a) Create the high level schedule and include the logical phases
  - b) Describe the duration of the project and any schedule constraints (i.e. holidays or other events)
- 5) Assumptions/Dependencies
  - a) Describe any organizational or study dependencies
  - b) Consider any developer or contractor requirements for supporting study efforts
  - c) Identify what assumptions are being made about the study and supporting elements.
- 6) Concurrence
  - a) Collected via email, with signatures and date
  - b) Concurrence indicates that both HFE and the sponsor agree on the objectives of the study before work begins to ensure that the results of the study address program office needs, including timeline

As the Contractor shall collaborate with other HFE Resources, some studies may be executed where the Study Proposal was crafted by another HFE Resource, but all related study materials shall be loaded to the same Effort Tracker entry.

The Study Plan shall minimally include:

- 1) Purpose of Study
  - a) Study Objectives
  - b) Applicable Methods, tools, and resources
- 2) Session script(s) or questions for users (questionnaire)
  - a) Target number and types of participants (for various user roles)
- 3) Data collection and analysis approach
  - a) Task success criteria if performing tasks
- 4) Project Timeline and Milestones
  - a) Sponsor connection points to review progress, risks, and responsibilities
- 5) Other project-specific parameters, such as:
  - a) Test procedures
  - b) Scenarios
  - c) Personas

The Study Report format (visual or written) shall vary depending on the study type (such as wireframes for design related studies) and customer preferences and can range from an Adobe InDesign, Adobe PDF, Excel workbook, a PowerPoint presentation, a Word document, diagrams, web content or other visual format. Regardless of format, the Contractor shall provide deliverables that are 508 Accessibility compliant and text editable by the Government, including reusable components for future work. All materials, including written and visual products produced by the Contractor shall be owned by the Government and be submitted using approved templates or branding. Studies including briefings and disposition of findings are expected to be associated with a PowerPoint presentation to support collaborative decision-making to identify solutions to usability problems. Studies including data analysis and collection of numerous quantifiable information elements are expected to be associated with an Excel workbook providing raw data and analyses summaries. The HFE minimum expectation for written reports shall follow this structure, adapted from the Human Factors and Ergonomics Society (HFES) conference proposal requirements (<http://cms.hfes.org/Events/Annual-Meeting/Call-for-Proposals.aspx#Forms>), and are expected to be associated with a Word document:

- **Introduction:** General statement to orient the reader to the specific problem and context, study personnel, background information, and relevant literature.
- **Method:** How the study was conducted, including participants, apparatus, and procedure (e.g., any tasks completed by participants).
- **Results:** Summarize the data collected, list any findings<sup>1</sup>, and/or include visual products<sup>2</sup> such as mock-ups.
- **Discussion:** Describe your analysis of the results, the implications, pertinent evidence-based recommendations, and study limitations and next steps.
- **References:** Provide full references for all citations used in the proposal in current edition American Psychological Association (APA) style.

The Contractor shall acquire agreement from the Government HFE Lead and Sponsor on format prior to execution and identify and communicate the key characteristics

required to meet each stakeholder's objectives for the study. For internal HFE operations work, the Government HFE Lead will determine if study proposals and plans are required in addition to the work item (visual or written report) itself. The Contractor shall document all initiated work, provide updates, and load the final Study Package in the HFE Effort Tracker SharePoint. The Contractor shall deliver the Government HFE Lead **app**roved proposal, study plan, and study report to the Sponsor, and perform a study debriefing call to answer questions should the Sponsor require. Sponsors have 30 days to review the study report before studies are marked as 'Completed'. Studies are scheduled once the study plan is approved by the Government HFE Lead. A study plan is established after Government HFE Lead and Sponsor concurrence of the study proposal is acquired.

The Contractor shall also perform an After-Action Review (AAR) and **sub**mit entries to the Lessons Learned Journal (LLJ) for all applicable opportunities for improvement for each study activity which the Contractor was actively engaged, including facilitating the AAR meeting, and document the materials in a Working Product, and include the study sponsor in the session.

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<sup>1</sup> The HFE basic definition of a finding has been adopted from the Nielsen Norman Group's, to include Takeaway, Prioritization, Description, Participant quote, Analysis, Evidence Based Recommendation, and Ownership and Measurement. (Nielsen Norman Group. (2017). Anatomy of a Usability Finding. UX Deliverables)

<sup>2</sup> Visual products are as described elsewhere in the PWS.

The AAR meeting shall make use of the proposal as a basis for discussion. Suggested questions for brainstorming include:

- Were we able to meet the objectives? Why or why not?
- Did we have the right stakeholders identified initially? If not, what might have allowed for that upfront?
- Were there technology issues that were preventable? If so, how?
- Was our mitigation of risks successful?
- Did our assumptions pan out?
- Did scope creep affect our outcomes? Could that have been avoided? If so, how?
- Were we able to keep to our original schedule? If not, why? Were there actions that could have been done to keep to the schedule better?
- Was communication within the team such that everyone was aware of the status, timeline, and issues?

- ☐ The LLJ is a SharePoint list maintained on HFE's main SharePoint site that the Contractor shall submit the title, problem, and recommendations for each lesson learned. The Contractor shall be responsible for ensuring all materials are loaded to the Effort Tracker and the LLJ, and shall notify the Government HFE Lead of known gaps of content, sourced or attributed as work products from other entities. The Effort Tracker entry is not marked complete until the LLJ content submitted, if applicable.

LLJ field	Description	Notes
<b>Title</b>	<i>Give the lesson a descriptive title.</i>	
<b>Problem</b>	<i>Describe the problem encountered. Why was it a problem? What were the (potential) effects on the project/study? Was any course of action pursued during the execution phase? Was anything tried that didn't work?</i>	
<b>Recommendations</b>	<i>Provide a recommendation from the project/study team to avoid the problem in the future.</i>	

**Problem:** The discussion shall consider both positive (“do more of this”) and negative (“avoid this in future”) lessons. For example, if you successfully mitigated a risk or

*effectively navigated a timeline change, please share those as well.*

*Recommendations: Recommendations shall be detailed enough that the Practice Committee or other Practitioners can put them to use. For example, if the team feels an item should be added to the study checklist, provide verbiage for that item.*

*Recommendations can be ideas for avoiding a problem in the future or they can reflect a good practice that mitigated a problem during the execution phase.*

Study Package deliverables are publicly accessible on the VA Network, while Working Products (e.g., drafts, AARs, study kick-offs) are only accessible to HFE Resources on the Effort Tracker.

## **5.1 PROJECT MANAGEMENT**

### **5.1.1 CONTRACTOR PROJECT MANAGEMENT PLAN**

The Contractor shall prepare and deliver a Contractor Project Management Plan (CPMP) that lays out the Contractor's approach, timeline and tools to be used in execution of this TO effort. The CPMP shall describe the Contractor's plans to support HFE studies and projects. The CPMP shall incorporate the tasks described in the PWS. The CPMP should take the form of both a narrative and graphic format that displays the schedule, milestones, risks and resource support. The CPMP shall also include how the Contractor shall coordinate and execute planned, routine, and ad hoc data collection reporting requests as identified within the PWS. The initial baseline CPMP shall be concurred upon and updated in accordance with Section B of the Contract. The Contractor shall update and maintain the VA Program Manager (PgM) approved CPMP throughout the PoP. The Contractor shall identify the primary contact point for all programmatic issues/concerns/status.

The Contractor shall document throughout the PoP and communicate weekly the decisions, expectations (assumptions), risks, actions, and issues log (DERAIL) aligned with each activity during study planning, execution, and closing phases. The Contractor shall establish and maintain a recurring Communication Schedule with stakeholders aligned with each assigned activity's objectives. The DERAIl and Communication Schedule shall be maintained on the Effort Tracker by the Contractor as a Working Product.

The Contractor shall expeditiously undergo sufficient background checks and complete required training in order to be granted access to VA's network and key resources used and managed by the HFE team within three (3) business days of receiving the notice of award. The Contractor shall communicate on an on-going manner the current status of contracting on-boarding including; last actions taken, next steps, and anticipated completion dates.

The CPMP shall also include a labor category staff roster identifying the following:

1. Employee Name
2. Personnel PIV Expiration
3. Personnel clearance level and adjudication date
4. Role

5. Project affiliation and assigned activities log
6. Personnel duty location address, alternate email, phone number

The Contractor shall continuously monitor performance and report any deviation to the COR or VA PgM.

**Deliverable:**

- A. Contractor Project Management Plan

### **5.1.2 REPORTING REQUIREMENTS**

The Contractor shall participate in, coordinate portions of, or lead meetings and briefings on assigned projects and studies while minimally documenting summary updates on the Effort Tracker. HFE is commonly a representative on an integrated project team, voicing the HCD approach and human factor expertise to a wide audience. Since the frequency and volume of associated meetings will differ by study, project, and engagement, the depth of reporting is variable. The Contractor shall maintain all materials created for individual studies as Working Products on the Effort Tracker.

During study execution, updates will be kept in the DERAILED, updated on the Effort Tracker as a Working Product that is maintained throughout project execution for each assigned project or study. The Contractor shall participate in joint reviews, track action items, schedule resources, and summarize technical and/or administrative problems encountered with recommendations for remediation. Each meeting or briefing will typically last one hour or less and most often be performed remotely via Skype/Lync, occurring once every week or every other week per project, depending on individual study complexity. The Contractor shall attend meetings as members of project or study teams and coordinate the discovery (scope definition), preparation (kick-off), execution (status) and closeout briefings for HFE studies during the project lifecycle. On all assigned recurring meetings, the Contractor shall be actively engaged, offering expert advice, suggestions, and recommendations on HFE issues as appropriate, including agreed upon timely responses to stakeholders for action items. On all assigned HFE coordinated briefings, the Contractor shall ensure the appropriate invites have been sent, a recommended agenda crafted, any materials shared at least two business days in advance (unless specified otherwise in the PWS), and appropriate follow-up on action items defined and distributed. The Contractor shall not commit the HFE Government team to additional studies or scope, but report such requests during the weekly Workload Assessment Meeting (WAM) and ensure potential requests for HFE services are forwarded to the appropriate channel (HFE group email to be provided upon award).

The Contractor shall summarize engagements with study activities via the Monthly Performance Report (MPR) that documents activities related to current studies, as well as anticipated upcoming engagements that are either planned or in the backlog. The Contractor shall ensure any impediments to ongoing work are readily visible and communicated. The Contractor shall seek remedies to impediments relative to their



impact and urgency as appropriate. The Contractor shall communicate the impediments as they occur, not waiting for the monthly report, and shall track resolutions in the MPR. The Contractor shall document the Functional Points assigned to active work, previously assigned Functional Points to completed work, and remaining Functional Points available on the Contract at each WAM.

The Contractor shall lead a WAM with the VA PgM each week for project summary and status discussions in preparation for the MPR submission. The weekly WAM shall include the following information:

1. Overall high-level assessment of study/project progress
2. Works in progress (WIP) with planned Study Package deliverables
3. Studies or projects recently completed since the last meeting
4. Planned studies or projects to begin in the next two (2) weeks, when applicable
5. Barriers to progress or inefficiencies experienced
6. New assignments

The MPR shall incorporate the prior WAM details for the prior full month's efforts, including corresponding changes made during the current reporting period, such as "Original target date for study report MM/DD/YYYY revised to MM/DD/YYYY on MM/DD/YYYY because of ... concurred upon by HFE Government Lead". Government feedback on prior reports shall be addressed in follow-on deliveries.

**Deliverable:**

- A. Monthly Performance Report

### **5.1.3 TECHNICAL KICKOFF MEETING**

The Contractor shall hold a technical kickoff meeting within 10 days after award. The Contractor shall present, for review and approval by the Government, the details of the intended approach, work plan, and project schedule for each effort. The Contractor shall specify dates, location (expected to be virtual), agenda (shall be provided to all attendees at least five (5) calendar days prior to the meeting), and meeting minutes including all presented materials (shall be provided to all attendees within three (3) business days after the meeting). The Contractor shall invite the Contracting Officer (CO), Contract Specialist (CS), COR, the VA PgM, and the HFE Government Lead.

**Deliverable:**

- A. Kickoff Agenda
- B. Kickoff Meeting Minutes

## **5.2 HUMAN FACTORS ENGINEERING SERVICES**

The Contractor shall support the HFE office in the provision of Human Factors Engineering Services to the numerous customers and sponsors engaged with OHI. The contractor shall support the design, development, testing, and implementation of various

clinician-facing and Veteran-facing health IT applications including, but not limited to, electronic health record systems, clinical reminders, consults, templates, order sets, alerts, patient discharge summaries, patient websites, print materials, and mobile applications. For some projects, the Contractor shall support the re-engineering of the clinical workflow or care delivery process into which the health IT applications must integrate. The Contractor shall provide support services across the project lifecycle utilizing the HCD approach, and at times provide services that spread across numerous activities concurrently, including: Specifying HIS Context of Use and User Requirements (5.2.1); Designing HIS Solutions (5.2.2); and Evaluating HIS Usability (5.2.3). Regardless of the effort, the Contractor shall provide Human Factors Engineering Services that aim to optimize overall system performance using the scientific method.

The Contractor shall consider and assess factors such as cognition, distractions, physical demands, and environments impact on patient care. The Contractor shall apply the definition of 'cognition' as the mental processes that enable users' memory, attention, and abilities to make decisions and problem solve. The Contractor shall consider the process limitations and recommend changes to improve cognition. Distractions are unavoidable in healthcare environments, and the Contractor shall assess means of limiting elements that divert attention from a user's focus. Physical demands include the stressors that inhibit physical and cognitive abilities and technical skills, for which the Contractor shall assess the physical demands users experience and their impacts on task performance during workflow analysis. The Contractor shall incorporate these elements into their findings and recommendations. The Contractor shall assess environmental factors associated with the care setting, including temperature, sound and lighting. The Contractor shall conduct human factors assessments that consider the environmental conditions of the care setting and its impact on safe and effective delivery.

The Contractor shall perform an analysis of targeted health information systems before implementation of a technology solution into a complex, safety-critical, healthcare delivery organization.

The Contractor shall perform requirements gathering for HIS that includes understanding and specifying the context of system use. The Contractor shall analyze clinical workflows, and shall analyze user jobs, tasks, and cognitive work (utilizing methods appropriate for improving patient-centered care). For example, cognitive task analysis is one family of methods that can be used to reveal the thinking involved in performing tasks in real-world contexts, and is well suited to understanding aspects of patient-centered care. The Contractor shall conduct various types of Time and Motion Studies to investigate and baseline current human-computer system interactions. The Contractor shall identify the Socio-technical factors likely to impact HIS usability, and those commonly addressed in system re-engineering using, for example, published practice guidelines for EHR implementation.

The Contractor shall support clinical workflow re-engineering and HIS design/customization activities to standardize care across VHA and between legacy and modernized EHR systems. The Contractor shall apply evidence-based guidance to engineer workflows that standardize clinical protocol, terminology, and processes to support team-based patient care, clinical decision-making, error tolerance, and system reliance. The Contractor shall apply evidence-based guidance to engineer workflows that enable knowledge management and the utilization of clinical data to inform care improvement and interoperability between VA Health Care systems and with the community. The Contractor shall perform an iterative design and assessment process to optimize workflow efficiency by streamlining clinical tasks and documentation, maintaining clinical data integrity and context, and minimizing workflow redundancies.

The Contractor shall follow industry practices for evaluating, testing, and validating the usability, physical and cognitive ergonomics of the EHR, HIS and other work systems in a holistic manner. The Contractor shall benchmark user performance measures on the legacy system and iterate the design and configuration of the new UI and work system as appropriate. The Contractor shall assess the HIS for compliance with evidence-based standards to support usability and to support effective clinician communication. The Contractor shall utilize and refine methods to evaluate and optimize the human-system interactions of a planned or deployed HIS.

The Contractor shall lead, manage, monitor, control and execute all aspects of a study; define test goals, recruit and screen participants, establish test plans and scripts, conduct assessments, perform data analysis, create reports, communicate findings, and make design and functionality recommendations to improve performance and system reliability. The Contractor shall adhere to published, evidence-based practices necessary to implement safe, highly usable HIS that supports effective and efficient delivery of patient-centered healthcare. "Published" or "evidenced-based" refers to materials published in a peer-reviewed journal, a human factors textbook, or by non-profit or governmental organization with a central mission to improve biomedical or health technology (i.e., AAMI, AMIA, ONC, HIMSS, etc.). Much of this work will include the novel application of HF related professional engineering practices and operations research functions on highly complex problems plaguing the health care system in both a tactical and strategic manner. The Contractor shall consult with users, business leads, user experience and user interface team members to lead, plan and execute a variety of studies and assessments including usability studies, ethnographic studies, error analysis, and cognitive walkthroughs, among others.

The Contractor shall apply human factors methods and analysis, mastering the fundamental concepts of observational, experimental, and correlational research methods that include both qualitative and quantitative data. The Contractor shall have expertise and skill applying statistical analysis, interviews, contextual inquiries, focus groups, inspections, evaluations, survey development, rapid ethnography, systems design, data coding and literature reviews. The Contractor shall identify and define the

gaps, risks, limitations, system constraints, functionalities, findings, lessons, and factors contributing to the productivity, comfort, motivation, safety and satisfaction of users.

The Contractor shall apply a multi-disciplinary approach to human factors testing, with knowledge from HF, HCI, usability, ethnography, and cognitive, social and organizational psychology to produce assessments and reports, and other elements of the study package as appropriate to specified study objectives.

Most studies shall be conducted virtually using the VA network and internet resources, although some studies shall be conducted at VA Medical Centers (VAMCs) or Community-Based Outpatient Clinics (CBOCs) in-situ, simulated in a lab, or in other face-to-face settings. The Contractor shall be able to apply human factors engineering, cognitive systems engineering, and resilience engineering.

The Human Factors Engineering Services requirements apply to the below sub-sections.

### **5.2.1 SPECIFYING HIS CONTEXT OF USE AND USER REQUIREMENTS**

VHA develops and acquires HIS products for use by Veterans, family caregivers, and a variety of clinical staff. To ensure that the HIT products are both useful and usable, VHA must have a deep understanding of intended users, users' goal-based needs for HIT applications, and the context of HIS application use (such as environment, workflow, and related HIT products). Requirements gathering for HIT products will involve understanding and specifying the context of system use and investigating highly complex problems that negatively impact care delivery.

The Contractor shall capture observations, data analysis, assumptions, and recommendations in a Study Package Deliverable that enables VHA project teams to target key functionality, optimize designs, prepare for a successful implementation, and encourage adoption. The targeted levels of granularity for analysis may include the user task, clinical workflow, or care delivery system; the scope and objective(s) of the effort engaged on will inform the appropriate level of analyses. These packages shall include analysis on the barriers to efficiency and risks to safety.

To provide VHA project teams the necessary information for designing safe, useful, and usable health information systems, the Contractor shall have the skills needed to apply human factors methods and analyses to execute single- and multi-method studies to;

- analyze clinical workflow and information flow, and uncover constraints to system efficiency and work-arounds, and shall produce as necessary, process models using notations such as Business Process Modelling Notation (BPMN), and information models using notations such as Unified Modeling Language (UML);
  - process models (utilizing BPMN) represent a logical and visual depiction of the organization's current state (As-Is) and desired future state (To-Be) processes, and shall be designed to support requirements development,

enterprise architecture development, HIS development, and business process re-engineering. Process models shall demonstrate a business flow with a sequential progress, and assist in identifying relationships, business rules, and information exchanges using constructs such as swim lanes, data objects, requirement linkages, events, and activities

- information models (utilizing UML) are visual representations of the logical categorization of business data elements and their relationships/dependencies on other data within the subject area, and group data using the constructs of classes, attributes and enumerations
- analyze the jobs, skills and work patterns for primary and secondary users of the proposed HIT, and shall document user's cognitive actions while applying the Critical Decision method, such as Decision/Judgement/Action-Requirements Table (DJART);
- analyze user task-flows that include physical and cognitive tasks and the tools / artifacts used. The analysis of user cognition and information processing will apply the science of human perception (visual and auditory systems) and cognition (mental representations, information processing models, decision making strategies) needed for effective design of clinical decision support systems;
- investigate and analyze impact of environmental and physical barriers to effective care delivery; apply socio-technical systems theory and the human-system interaction model to identify environmental factors with potential impacts to HIS design and workspace layout;
- investigate causes of HIT use error and identify factors that negatively impact user attention, stress, physical demands, cognition, and decision-making;
- specify the gaps, risks, limitations, system constraints, functionalities with the As-Is legacy solutions and corresponding requirements for the To-Be future state to optimize productivity, comfort, motivation, safety and satisfaction of users;
- specify representative test cases and edge-case scenarios for evaluating the effectiveness of the To-Be future state. The Contractor shall document clear Scenarios (including common, complex and high-risk contexts of use) that reflect the scope of the user needs in all assigned projects, and target appropriate levels of detail for the intended purpose of scenario generation (e.g., as-is, to-be, discovery, or testing); and
- baseline clinical workflow and user performance measures, and conduct various types of time-and-motion studies on human-computer/human-system interactions with the legacy solutions.

Below are representative methods that the Contractor shall conduct in accordance with published human factors engineering practices:

- Literature reviews
- Clinical observation studies
- Time and motion studies
- Contextual inquiries
- Stakeholder interviews
- Questionnaires
- Focus groups
- Diary studies
- GOMS (Goals, Operators, Methods, and Selection) modeling
- Job and work analysis
- Hierarchical task analysis
- Cognitive task analyses
- Affinity diagramming
- Qualitative and quantitative data collection and analysis

**Deliverables:**

The Contractor shall perform Specifying HIS Context of Use and User Requirements work as part of a Study Package- this includes a study proposal, study plan, and study report as defined in PWS 5.0.

- A. Study Package
- B. Clinical Study Package

## **5.2.2 DESIGNING HIS SOLUTIONS**

The HFE team provides a wide range of human-system interaction design support services for VHA HIS projects. Design solutions involve various aspects of the overall complex safety-critical health care system that may pertain to patient care services, clinical workflows, clinical information flows, user task-flows, and the supporting health IT products (including legacy VistA/CPRS, mobile applications, websites, medical devices, wearables and VA's new EHR system among other emerging applications).

The Contractor shall produce HIS design solutions using an iterative design process to generate a Study Package Deliverable that includes design objectives, data and assumptions about the context of use, user requirements, design artifacts based on evidence-based standards, usability and safety risks, recommendations for implementation, recommendations for future enhancements, and other materials that enables VHA project teams to target key functionality, optimize designs for overall human-system performance, prepare for a successful implementation, and encourage adoption. The targeted levels of granularity for HIS design may include the user task, clinical workflow, or care delivery system; the scope and objective(s) of the effort engaged on will inform the appropriate level of analyses.

The Contractor shall utilize an iterative design process to produce HIS solutions. The Contractor shall vary the visual, interactive, and content fidelity of each assigned UI design activity to match study objectives and integrate within that project's lifecycle, focusing on the value benefit for sponsored work in the available timeframes.

Throughout the design process, the Contractor shall gauge how well proposed designs will enable intended users to carry out work effectively and efficiently. Design iterations will be informed by feedback from stakeholders, SMEs, end users, usability assessments, modeling, and simulations (as well as the techniques and methods described in sections 5.2.1 and 5.2.3).

To provide VHA project teams the necessary information for designing safe, useful, and usable systems, the Contractor shall have the skills needed to apply human factors and systems reengineering methods to execute single- and multi-method studies to;

- Collect, maintain, and leverage information and assumptions pertinent to the proposed design, including information about the context of use and legacy applications (such as usability and safety issues, quality measures, and baseline performance measures). Recognize gaps in information needed for HIS design; throughout the design process initiate or request studies as needed to fill information gaps or validate assumptions about the context of use.
- Apply analysis from context of use;
  - Where the Contractor shall refer to data from earlier cognitive work analysis from 5.2.1 activities to ensure workflows address communication needs with external providers.
  - Where the Contractor shall incorporate ergonomics when iterating design to ensure the physical, cognitive and environment are accounted for.
  - And for HIT products intended for clinician users, effective and efficient work must account for tasks that are part of a clinical workflow carried out in the context of clinical environments. In these cases, the Contractor shall ensure that socio-technical factors impacting the human-computer interaction (HCI) have been accounted for in the design process.
- Apply design thinking with stakeholders, end users, subject matter experts, and technologists to envision collaborative, patient-centered healthcare delivery systems.
- Capture and specify the intended value proposition of the proposed HIS and specify the HIS design objectives needed to achieve the stated value proposition.
- Support the creation of HIS service design artifacts (such as User Journey Maps, Customer Experience Maps and Service Blueprints) that enable a shared vision of the intended patient experience.
- Utilize existing Personas as appropriate, and facilitate creation of new Personas as aligned with project objectives.
- Support the reengineering of clinical workflows that optimize workflow efficiency clinical data utilization, promote care team coordination and decision-making, and, enhance patient safety.

- Support the creation of Storyboards and User/Stakeholder Maps that align with reengineered workflows and/or envisioned healthcare services.
- UI Design
  - The Contractor shall also design HIT products, processes, workflows, or systems within the range and constraints of evidence-based human performance capabilities and limitations (as found in physical and cognitive ergonomics literature). Design considerations for this contract shall be limited to systems having a human interface although some synthesis reporting may include data from, for example, network or server performance.
  - Conduct rapid, iterative UI prototyping that supports seamlessly integration of clinical workflow, information flow, and user task-flows.
- Apply Standards
  - Standards for clinical workflow diagrams and clinical processes, including standard terminologies using existing ontologies (e.g., ICD-10, SNOMED)
  - Standards for clinical data formats and representations, including HL7's Fast Healthcare Interoperability Resources (FHIR) and VHA's Health Factors and Vista Fileman Packages.
  - Apply evidence-based standards for human-system integration and user-interface design
  - The Contractor shall follow conventions for visual diagramming of user interactions and reference existing standards for user interface design.
- Apply feedback
  - The Contractor shall include results of findings and corresponding proposed changes to design of relevant/applicable HIT products, processes, workflows, or systems. The Contractor shall synthesize the findings, insights, and recommendations for each study.
  - The Contractor shall incorporate feedback on UI designs from end users, usability practitioners, stakeholders, and SMEs to resolve problems, mitigate risks, and incorporate design enhancements that improve user effectiveness, efficiency, and satisfaction.

Below are representative methods that the Contractor shall conduct in accordance with published practices from human factors engineering, industrial engineering, cognitive systems engineering, and resiliency engineering:

- Design thinking
- Brainstorm sessions
- Patient experience mapping
- Story mapping
- Conceptual modeling
- Workflow reengineering / cognitive system reengineering
- Storyboarding
- Participatory design



- Parallel (A/B alternative) design
- User interface design (wireframes, functional prototypes)
- Information architecture (Card sorting, information design)
- HIS configuration

**Deliverables:**

The Contractor shall perform HIS Design work as part of a Study Package- this includes a study proposal, study plan, and study report as defined in PWS 5.0.

A. Study Package

B. Clinical Study Package

**5.2.3 EVALUATING HIS USABILITY**

The Contractor shall provide expertise for evaluating HIS usability and to assess and validate the usability of a VA application or system in the context of its intended use in a production environment in accordance with usability testing standards in the International Organization for Standardization (ISO) standard 9241 part 11 (ISO 9241-11) <sup>3</sup> and HF practices and procedures. The Contractor shall plan, prepare, conduct, analyze, report, and debrief the results of usability assessments and HF evaluations. The Contractor shall provide qualitative and quantitative data collection and analysis, error analysis, application of socio-technical systems theory, and facilitation for session moderation. Usability Evaluation activities require approved, clearly specified test objectives and a description of how the planned activities will meet the objectives. Usability Assessments may occur across the project lifecycle and be focused on usability by measuring efficiency, effectiveness, satisfaction, and safety, depending on project objectives. This work is expected to be ongoing during the period of performance.

The Contractor shall perform Usability Assessments (e.g., heuristic evaluations, usability walkthroughs, cognitive walkthroughs, and pluralistic walkthroughs, among others) and Usability Testing (Formative and Summative) with both Qualitative and Performance-based approaches on newly developed, prototyped, or existing systems, depending on project objectives. The Contractor shall align appropriate methods to the study objectives, for example, to determine when think aloud protocols match data collection needs to meet study objectives. Furthermore, the Contractor shall plan for the appropriate study logistics and coordinate the necessary data collection requirements in advance, such as recording voice, video, screen capture, keystroke monitoring, facial expressions, or eye-tracking. The Contractor shall follow HFE practices and appropriate regulatory policies, such as Paperwork Reduction Act (PRA), regarding usability testing, interviews, questionnaires, and consent for use of picture and/or voice. The Contractor shall capture the necessary information to provide a rich, qualitative

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<sup>3</sup> The standard 9241 part 11 refers to performing usability testing to identify “the extent to which a product can be used by specified users to achieve goals with effectiveness, efficiency, and satisfaction in a specified context of use.”

assessment that uncovers fundamental usability and workflow integration issues that is not possible from a performance-based approach. The Contractor shall perform performance-based testing that can provide statistical evidence of user performance, and for retested applications or comparisons between applications the Contractor shall document the impact to the baseline user performance for established usability metrics.

The Contractor shall propose appropriate usability metrics to meet the project objectives, and execute the requisite data collection for the agreed upon metrics. The Contractor shall incorporate metrics definition in the project preparation phase to ensure all data needs are collected from the initiation of the study. The Contractor shall ensure that the definitions for tasks, task success, and the data collection methods are designed to ensure adequate assessment and generation of recommendations. Some studies may require data collection for various user groups in multiple roles, and potentially distinguish novice from expert users. The Contractor shall define the usability metrics and execute the evaluation to accommodate this variation to capture all the necessary information. Sample metrics when involving user participants include:

- Task success (direct, indirect, failure, etc.)
- Mouse clicks/keystrokes
- Optimal path alignment, tree testing
- First click rate
- Time on task
- Novice to expert ratio
- Errors committed
- User subjective satisfaction
- System Usability Scale (SUS) and Computer System Usability Questionnaire (CSUQ)

HFE usability testing provides an “arms-length” evaluation that is independent from system design development activities. Testing will evaluate the usability of VHA HIT products, processes, workflows, or systems that are at the end-stage of development, or already deployed at VHA hospitals, clinics and specialty service centers (i.e., Veterans Crisis Line). The HIT could be VHA developed or purchased, and may or may not have had prior involvement by HFE. This independent (‘arms-length’) perspective is particularly important when conducting summative usability tests (the validation of system usability), in order to avoid bias from HFE resources previously involved in design services. For this purpose, those design resources are generally excluded from performing usability assessments. The Contractor shall provide sufficient resources to enable distinct engagement teams across the execution of Usability Assessment activities.

For both formative and summative usability tests, the Contractor shall provide a Study Report containing Findings which shall be written using the HFE report template which adheres to NIST Interagency/Internal Report (NISTIR) 7742 Common Industry Format (CIF), an established standard format for reporting the results of summative usability

tests. Findings shall incorporate application of sociotechnical systems theory and are therefore not limited to the UI itself. Study Reports shall also include recommendations for options to address findings. These recommendations shall be discussed and dispositioned with the sponsor and development team. Similar to the expected breadth of findings, recommendations shall take into account sociotechnical elements such as policy, culture, and hardware.<sup>4</sup>

For studies involving no user participants, and only expert review, the Contractor shall identify and describe potential usability problems, the violations of the usability heuristics, and provide suggestions to improve the system usability, utility and design related to the report findings. The Contractor shall make recommendations to whether further user testing would be advisable given the identified findings. The Contractor shall be able to execute subsequent summative testing, keystroke level modeling, time-motion studies, and in-situ usability assessments when project objectives indicate such alignment.

Each Study Package shall include the test script, details regarding the number and types of participants, task success criteria, and other project-specific parameters (e.g., test objectives, test procedures, and scenarios) as part of the study plan; the raw data and preliminary findings (e.g., time on task measurements, mouse clicks, keystrokes) and findings such as themes produced from an initial analysis of the data, with a preliminary review of the data as part of the study report; and any updates based on the disposition with the customer for the final study report.

Below are representative methods that the Contractor shall conduct in accordance with published human factors engineering practices:

- Usability inspections/ design audit
- Usability walkthroughs
- Cognitive walkthroughs
- Formative usability testing
- Keystroke level modeling
- Summative usability testing
- In-situ usability testing
- Usability observations

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<sup>4</sup> The format and metrics outlined by the CIF are consistent with the ISO 9241-11 and therefore warrants VA adhering to the CIF to assure good usability practices have been followed, sufficient information exists to judge the validity of the results, tests replicated following the CIF will return similar results, as well as capturing measures of effectiveness, efficiency, and satisfaction. An example of a validation test would be to accomplish the summative usability testing required by the Office of the National Coordinator Health Information Technology (ONC) 2014 Edition of Safety-enhanced Design.

**Deliverables:**

The Contractor shall perform Evaluating HIS Usability work as part of a Study Package- this includes a study proposal, study plan, and study report as defined in PWS 5.0.

- A. Study Package
- B. Clinical Study Package

**5.3 COORDINATING ENGAGEMENTS, PROJECTS, AND STUDIES**

The Contractor shall provide project coordination services across multiple, simultaneous activities of varying complexity for Coordinating Engagements, Projects, and Studies. The Contractor shall perform VHA employee (such as clinicians, not Veterans) participant recruitment and scheduling coordination, technology set-up for virtual studies, logistics planning for in-person or remote sessions, data recording, coding and analysis, report writing, technical editing/proofreading for formal PR and WG, meeting scheduling and agenda preparation, study recommendations disposition tracking, engagement summaries preparation, publishing support, and graphical design. This work is expected to be ongoing during the period of performance. Note, HFE does not perform "Research" as defined by VHA Office of Research & Development (ORD), and HFE follows VA and VHA regulations and policies (<http://www.va.gov/vhapublications/publications.cfm?pub=2>). Each study participant is aligned to study objectives based on study specific criteria detailed in the Study Proposal and clearly defined in the Study Plan.

The Contractor shall perform activities isolated from other tasks under this PWS section, for example, if the Contractor is only assigned a Peer Review task, the Contractor shall submit the deliverable under this PWS section. Additionally, should the Contractor perform a study kick-off call that does not proceed to execution, the Contractor shall deliver the study kick-off materials under this activity.

The Contractor shall perform assigned tasks either as an independent task or as a continuing series of support for ongoing engagements. The Contractor shall perform the following activities and provide the collection of related support materials with the associated Study Package or Work Products based upon the Government's need on a per-project basis:

Activity	Examples of Tools used	Work product
Configure and test technology(ies) to be used in studies	Morae, Adobe Connect, Microsoft Lync/Skype, Optimal Workshop, VANTS telephone bridge, WebEx, Survey Monkey	<b>Study Preparation</b> <ol style="list-style-type: none"> <li>1) Notes from configuration and test session documenting any issues encountered and how resolved</li> <li>2) Study checklist confirming successful testing of study configuration</li> </ol>
Data recordings, such as audio recordings and video recordings	Morae, Adobe Connect, Microsoft Lync, UserZoom, WebEx, MS Word, pen and paper	<b>Study Recordings</b> <ol style="list-style-type: none"> <li>1) Video recordings captured via Morae or other tool with quality verified</li> <li>2) Audio recordings captured via Adobe Connect, Lync/Skype for Business, WebEx or other tool with quality verified</li> <li>3) Notes taken that adhere to script used during test session. Notes will be delivered in MS Word or Excel format, depending on study needs</li> </ol>
Data coding and analysis	MS Word, Excel, 'PSPP'	<b>Data Analysis</b> <ol style="list-style-type: none"> <li>1) Coding scheme: Coding schemes are primarily the responsibility of the study lead, but other members of the team may be asked to independently code, or minimally, to audit the codes, in order to ensure higher reliability of the coding scheme</li> <li>2) Identify and document major themes and other findings identified by data analysis: Data analysis is primarily the responsibility of the study lead, but other members of the team will be asked to independently analyze or validate in order to ensure higher reliability of reported findings</li> </ol>
Report writing	MS Word, Excel, PowerPoint	<b>Report Generation</b> <ol style="list-style-type: none"> <li>1) Reports: Report writing is primarily the responsibility of the study lead, but other members of the team will review and contribute in order to ensure higher quality and completeness of reported findings</li> </ol>

Activity	Examples of Tools used	Work product
Technical editing/proofreading	MS Word, Excel, PowerPoint	<b>Technical Editing</b> <ol style="list-style-type: none"> <li>1) Edited/proofed documents: Contractor may be asked to edit and/or proofread a variety of documents produced by the HFE team including study proposals and study reports.</li> <li>2) 508 compliance review, PR and WG: The Contractor may be assigned content for review on various materials, for which identifying, documenting, suggesting and editing materials may be required.</li> </ol>
Meeting scheduling/agenda preparation	MS Outlook or similar, telephone, MS Word, MS Lync, VANTS, Adobe Connect, WebEx	<b>Logistics Planning</b> <ol style="list-style-type: none"> <li>1) Calendar appointments with agendas if necessary: Contractor may be asked to schedule meetings for purposes such as presenting study results to a customer, or establishing study kick-off, touch points, or close out calls.</li> <li>2) Meeting agenda: Contractor may be asked to develop agenda for a meeting and include as part of the meeting appointment. Government staff will determine key agenda items for inclusion</li> </ol>
Study recommendation disposition	MS Word, Excel, SharePoint	<b>Study Disposition</b> <ol style="list-style-type: none"> <li>1) Updated Effort Tracker recommendations: Disposition of study recommendations must be tracked. This means, for example, that a record is maintained of whether the recommendation was implemented in the current product version, held for inclusion in a future product version, rejected, etc.</li> </ol>
Engagement Synopsis	MS Word, Excel, SharePoint MS PowerPoint	<b>Study Review</b> <ol style="list-style-type: none"> <li>1) Summary Materials: The Contractor shall provide summary materials or engagement level integrated workbooks that describe the complete history of HFE activities related to a particular topic. This material may be used to debrief new sponsors, or provide examples to new partners on the types of engagements HFE has supported.</li> </ol>

Activity	Examples of Tools used	Work product
Publications, White Papers, Articles, Newsletter Posts, Spotlight Announcements, Presentations, Brown Bags and Posters	MS Word, Excel, MS PowerPoint, MS Publisher, Adobe	<b>Study Publication and Presentation</b> 1) Publication materials: The Contractor shall support concepts, drafting, revisions, and researching, submitting, and presenting materials relevant for public release on associated projects. This material may be iterated amongst various pathways and across multiple channels.
Graphical Design, and Modelling	Adobe InDesign, MS Publisher, MS Excel, MS Word, MS PowerPoint, MS Visio	<b>Design Materials</b> 1) Graphical Design: The Contractor shall support the conceptualizing, provisioning, and augmentation of graphical components and visualizations used within HFE reporting materials, such as Icons, Graphs, Silhouettes, Bordering, Animations, Thumbnails, Storyboards, Process Diagrams, Headers, Branding, and Web Page images. Access to open source image repositories is advised, and the Contractor shall align all work to the current VA Style Guide and HFE procedures.
Study Kick-off and FPE	Adobe InDesign, MS Publisher, MS Excel, MS Word, MS PowerPoint, MS Visio	<b>Study Kick-off</b> 1) Kick-off materials: The Contractor shall support the study kick-off meeting and review the provided information in development of the FPE.

**Deliverables:**

The Contractor shall perform Coordinating Engagements, Projects, and Studies work as assigned, and provide the necessary support and materials based on assigned activities.

- A. Study Preparation
- B. Study Recordings
- C. Data Analysis
- D. Report Generation
- E. Technical Editing
- F. Logistics Planning
- G. Study Disposition

- H. Study Review
- I. Study Publication and Presentation
- J. Design Materials
- K. Study Kick-off and FPE

#### **5.4 MATURING CONTENT FOR THE USER EXPERIENCE (UX) GUIDE**

The Contractor shall support the continued creation, publication, and curation of content in HFE's UX Guide, while continuously improving the UX Guide operational effectiveness in meeting the needs of users. The guide is intended for use by VISN- and field-based informatics staff, and provides evidence-based methods, tools and techniques for applying human-centered design to HIT acquisition projects, application design projects, and HIS configuration and implementation projects. HFE anticipates the UX Guide will also be used by business stakeholders and development teams.

UX Guide Content includes:

- Strategies for applying human-centered design across the project lifecycle, with from concept design through implementation.
- Evidence-based usability principles – such as UT Health's General Design Principles & Guidelines (<https://sbmi.uth.edu/nccd/ehrusability/design/guidelines/>)
- User interface design patterns – such as a pattern for showing out-of-range values (e.g. patient lab values that are higher or lower than the normal ranges)
- Re-usable artifacts developed by other VA projects - such as user personas, scenarios, and journey maps
- HCD Methods (such as a Heuristic Evaluation or User Interview) that describe how and why a method is used, instructions for various techniques, and downloadable tools
- HCD case studies that describe a project objectives, approaches, challenges, outcomes, and lessons learned.

At the conclusion of any project/task completed under this contract, the Contractor shall submit newly developed materials to the UX Guide. For example, personas and scenarios created for a project that could be re-used for other projects would be submitted to the UX Guide. The contractor shall modify existing UX Guide materials to reflect improvements in human-centered design practices. For example, usability problems uncovered in a test of an application (such as a clinical reminder dialogue template) could prompt an update to the published design guidance for that application type, enabling field-based Clinical Informaticists to avoid similar problems in the future.

The Contractor shall create and extend UX Guide content as needs are identified and prioritized by intended users and stakeholders. User stories and job stories shall be maintained to capture user need, and to ensure that various methods and tools in the UX Guide integrate across a project's design, development, and implementation phase.



The Contractor shall support the maintenance of and enhancement of the UX Guide's content and knowledge management systems (e.g., WordPress, SharePoint). The contractor shall maintain and follow a quality assurance process for UX Guide content that addresses both the quality of information (maintained in XML) and the usability of how information is presented (using HTML). For example, some UX Guide content types (such as design principles) shall require a vetting by subject matter experts and shall be assigned a strength of evidence rating.

The Contractor shall provide a summary of UX Guide support and a planned schedule of activities monthly in the UX Guide Report. The report shall include content management efforts from the preceding and future month, including any newly created, modified, and externally referenced content additions. The Contractor shall report deviations from planned activities and accomplishments which shall be readily visible in the report, with details provided on the cause of variation. The report shall include the information management functions the Contractor performed that separate the UX Guide content information from the presentation layers necessary for the continued knowledge management and transfer. The report shall include the intended strategy for user experience activities to ensure the UX Guide is meeting the needs of users and shall detail the community engagement functions that are supporting a growing community of practice. The report shall outline the backlog of supporting efforts to improve the UX Guide- including, content creation, refinements, and testing activities to support continuous improvement of the UX Guide.

The UX Guide URL will be provided upon contract award.

**Deliverables:**

The Contractor shall perform Maturing Content for the UX Guide work as assigned, and provide the necessary support and materials based on assigned activities.

- A. UX Guide Content
- B. UX Guide Report

## **Rights in Deliverables**

The Contractor is required to deliver reports, technical data, configurations, documentation or other information, during contract performance. The Government shall receive Unlimited Rights in intellectual property first produced and delivered in the performance of this contract in accordance with FAR 52.227-14, Rights In Data-General (MAY 2014). This includes all rights to source code and any and all documentation created in support thereof.

## 6.0 GENERAL REQUIREMENTS

### 6.1 PERFORMANCE METRICS

The table below defines the Performance Metrics associated with this effort.

Performance Objective	Performance Standard	Acceptable Performance Levels
A. Technical Needs	<ol style="list-style-type: none"> <li>Shows understanding of requirements</li> <li>Efficient and effective in meeting requirements</li> <li>Meets technical needs and mission requirements</li> <li>Offers quality services/products</li> </ol>	Satisfactory or higher
B. Project Milestones and Schedule	<ol style="list-style-type: none"> <li>Quick response capability</li> <li>Products completed, reviewed, delivered in timely manner</li> <li>Notifies customer in advance of potential problems</li> </ol>	Satisfactory or higher
C. Project Staffing	<ol style="list-style-type: none"> <li>Currency of expertise</li> <li>Personnel possess necessary knowledge, skills and abilities to perform tasks</li> </ol>	Satisfactory or higher
D. Value Added	<ol style="list-style-type: none"> <li>Provided valuable service to Government</li> <li>Services/products delivered were of desired quality</li> </ol>	Satisfactory or higher

The Government will utilize a Quality Assurance Surveillance Plan (QASP) throughout the life of the contract to ensure that the Contractor is performing the services required by this PWS in an acceptable manner. The Government reserves the right to alter or change the QASP at its own discretion. A Performance Based Service Assessment Survey will be used in combination with the QASP to assist the Government in determining acceptable performance levels. The COR will determine if the performance of the Contractor is below a metric standard and deem it unacceptable. The COR will then notify the Contracting Officer.

## **6.2 SECTION 508 – ELECTRONIC AND INFORMATION TECHNOLOGY (EIT) STANDARDS**

The following Section 508 Requirements supersede Addendum A, Section A3 from the T4NG Basic PWS.

The Section 508 standards established by the Architectural and Transportation Barriers Compliance Board (Access Board) are incorporated into, and made part of all VA orders, solicitations and purchase orders developed to procure Electronic and Information Technology (EIT). These standards are found in their entirety at: <http://www.section508.gov> and <http://www.section508.gov/acquisition-regulations>. A printed copy of the standards will be supplied upon request. The Contractor shall comply with the technical standards as marked:

- ☒ § 1194.21 Software applications and operating systems
- ☒ § 1194.22 Web-based intranet and internet information and applications
- ☒ § 1194.23 Telecommunications products
- ☒ § 1194.24 Video and multimedia products
- ☒ § 1194.25 Self contained, closed products
- ☒ § 1194.26 Desktop and portable computers
- ☒ § 1194.31 Functional Performance Criteria
- ☒ § 1194.41 Information, Documentation, and Support

Offerors shall use the appropriate Section 508 Standards Checklists to ensure conformance with Section 508 Standards. The Standards Checklists along with additional information are available at [http://www.section508.va.gov/section508/Standards\\_Checklist.asp](http://www.section508.va.gov/section508/Standards_Checklist.asp).

Automated test tools and manual techniques are used in the VA compliance assessment. Additional information concerning tools and resources can be found at <http://www.section508.va.gov/section508/Resources.asp>.

The Government reserves the right to independently test for 508 Compliance before delivery. The Contractor shall be able to demonstrate 508 Compliance upon delivery.

### **6.2.1 EQUIVALENT FACILITATION**

Alternatively, offerors may propose products and services that provide equivalent facilitation, pursuant to Section 508, subpart A, §1194.5. Such offerors will be considered to have provided equivalent facilitation when the proposed deliverables result in substantially equivalent or greater access to and use of information for those with disabilities.

## **6.2.2 COMPATIBILITY WITH ASSISTIVE TECHNOLOGY**

The Section 508 standards do not require the installation of specific accessibility-related software or the attachment of an assistive technology device. Section 508 requires that the EIT be compatible with such software and devices so that EIT can be accessible to and usable by individuals using assistive technology, including but not limited to screen readers, screen magnifiers, and speech recognition software.

## **6.3 ENTERPRISE AND IT FRAMEWORK**

The Contractor shall ensure Commercial-Off-The-Shelf (COTS) product(s), software configuration and customization, and/or new software are PIV-enabled by accepting HSPD-12 PIV credentials using VA Enterprise Technical Architecture (ETA), <http://www.ea.oit.va.gov/EAOIT/OneVA/EAETA.asp>, and VA Identity and Access Management (IAM) approved enterprise design and integration patterns, [http://www.techstrategies.oit.va.gov/docs\\_design\\_patterns.asp](http://www.techstrategies.oit.va.gov/docs_design_patterns.asp). The Contractor shall ensure all Contractor delivered applications and systems are compliant with VA Identity Management Policy (VAIQ# 7011145), Continued Implementation of Homeland Security Presidential Directive 12 (VAIQ#7100147), and VA IAM enterprise identity management requirements (IAM Identity Management Business Requirements Guidance document), located at <https://www.voa.va.gov/documentlistpublic.aspx?NodeID=514>. The Contractor shall ensure all Contractor delivered applications and systems provide user authentication services compliant with NIST Special Publication 800-63-2, VA Handbook 6500 Appendix F, "VA System Security Controls", and VA IAM enterprise requirements for both direct and assertion based authentication. Direct authentication at a minimum must include Public Key Infrastructure (PKI) based authentication supportive of both Personal Identity Verification (PIV) and Common Access Card (CAC). Assertion authentication at a minimum must include Security Assertion Markup Language (SAML) token authentication and authentication/account binding based on trusted headers. Specific Identity and Access Management PIV requirements are set forth in OMB Memoranda M-04-04 (<http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy04/m04-04.pdf>), M-05-24 (<http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-24.pdf>), M-11-11 (<http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-11.pdf>), National Institute of Standards and Technology (NIST) Federal Information Processing Standard (FIPS) 201-2, and supporting NIST Special Publications. For applications, software, or hardware that cannot support PIV authentication, a Risk Based Decision must be approved by the Deputy Assistant Secretary for Information Security.

The Contractor solution shall support Internet Protocol Version 6 (IPv6) in accordance with the directive issued by the Office of Management and Budget (OMB) on September 28, 2010 (<https://cio.gov/wp-content/uploads/downloads/2012/09/Transition-to-IPv6.pdf>), August 2, 2005 (<http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-22.pdf>), and (<http://www.cybertelecom.org/dns/ipv6usg.htm>). IPv6 technology, in

accordance with the USGv6: Technical Infrastructure for USGv6 Adoption (<http://www.nist.gov/itl/antd/usgv6.cfm>) and the NIST SP 800 series applicable compliance (<http://csrc.nist.gov/publications/PubsSPs.html>) shall be included in all IT infrastructures, application designs, application development, operational systems and sub-systems, and their integration. In addition to the above requirements, all devices shall support dual stack connectivity without additional memory or other resources being provided by the Government, so that they can function in a mixed environment. All public/external facing servers and services (e.g. web, email, DNS, ISP services, etc.) shall support native IPv6 users, and all internal infrastructure and applications shall communicate using native IPv6 operations. Guidance and support of improved methodologies which ensure interoperability with legacy protocol and services in dual stack solutions, in addition to OMB/VA memoranda, can be found at: <https://www.voa.va.gov/documentlistpublic.aspx?NodeID=282>.

The Contractor solution shall meet the requirements outlined in Office of Management and Budget Memorandum M08-05 mandating Trusted Internet Connections (TIC) (<http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2008/m08-05.pdf>), M08-23 mandating Domain Name System Security (NSSEC) (<http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2008/m08-23.pdf>), and shall comply with the Trusted Internet Connections (TIC) Reference Architecture Document, Version 2.0 ([http://www.dhs.gov/sites/default/files/publications/TIC\\_Ref\\_Arch\\_v2%200\\_2013.pdf](http://www.dhs.gov/sites/default/files/publications/TIC_Ref_Arch_v2%200_2013.pdf)).

#### **6.4 INFORMATION TECHNOLOGY USING ENERGY-EFFICIENT PRODUCTS**

The Contractor shall comply with Sections 524 and Sections 525 of the Energy Independence and Security Act of 2007; Section 104 of the Energy Policy Act of 2005; Executive Order 13514, "Federal Leadership in Environmental, Energy, and Economic Performance," dated October 5, 2009; Executive Order 13423, "Strengthening Federal Environmental, Energy, and Transportation Management," dated January 24, 2007; Executive Order 13221, "Energy-Efficient Standby Power Devices," dated August 2, 2001; and the Federal Acquisition Regulation (FAR) to provide ENERGY STAR®, FEMP designated, low standby power, and Electronic Product Environmental Assessment Tool (EPEAT) registered products in providing information technology products and/or services.

The Contractor shall ensure that information technology products are procured and/or services are performed with products that meet and/or exceed ENERGY STAR, FEMP designated, low standby power, and EPEAT guidelines. The Contractor shall provide/use products that earn the ENERGY STAR label and meet the ENERGY STAR specifications for energy efficiency. Specifically, the Contractor shall:

1. Provide/use ENERGY STAR products, as specified at [www.energystar.gov/products](http://www.energystar.gov/products) (contains complete product specifications and updated lists of qualifying products).

2. Provide/use the purchasing specifications listed for FEMP designated products at [www.femp.energy.gov/procurement](http://www.femp.energy.gov/procurement). The Contractor shall use the low standby power products specified at [www.femp.energy.gov/procurement](http://www.femp.energy.gov/procurement).
3. Provide/use EPEAT registered products as specified at [www.epeat.net](http://www.epeat.net). At a minimum, the Contractor shall acquire EPEAT® Bronze registered products. The acquisition of Silver or Gold EPEAT registered products is encouraged over Bronze EPEAT registered products. EPEAT registered products are required to meet the technical specifications of ENERGY STAR, but are not automatically on the ENERGY STAR qualified product lists. The Contractor shall ensure that applicable products are on both the EPEAT Registry and ENERGY STAR Qualified Product Lists.
4. The Contractor shall use these products to the maximum extent possible without jeopardizing the intended end use or detracting from the overall quality delivered to the end user.

The following is a list of information technology products for which ENERGY STAR, FEMP designated, low standby power, and EPEAT registered products are available:

1. Computer Desktops, Laptops, Notebooks, Displays, Monitors, Integrated Desktop Computers, Workstation Desktops, Thin Clients, Disk Drives
2. Imaging Equipment (Printers Copiers, Multi-Function Devices, Scanners, Fax Machines, Digital Duplicators, Mailing Machines)
3. Televisions, Multimedia Projectors

This list is continually evolving, and as a result is not all-inclusive.

#### **ADDENDUM A – General Notes**

**APPLICABLE PARAGRAPHS TAILORED FROM: *THE VA INFORMATION AND INFORMATION SYSTEM SECURITY/PRIVACY LANGUAGE, VA HANDBOOK 6500.6, APPENDIX C, MARCH 12, 2010***

##### **B1. GENERAL**

Not Applicable.

##### **B2. ACCESS TO VA INFORMATION AND VA INFORMATION SYSTEMS**

Not Applicable.

##### **B3. VA INFORMATION CUSTODIAL LANGUAGE**

Not Applicable.

**B4. INFORMATION SYSTEM DESIGN AND DEVELOPMENT**

Not Applicable.

**B5. INFORMATION SYSTEM HOSTING, OPERATION, MAINTENANCE, OR USE**

Not Applicable.

**B6. SECURITY INCIDENT INVESTIGATION**

Not Applicable.

**B7. LIQUIDATED DAMAGES FOR DATA BREACH**

Not Applicable.

**B8. SECURITY CONTROLS COMPLIANCE TESTING**

Not Applicable.

**B9. TRAINING**

ACCESS TO PERSONALLY IDENTIFIABLE INFORMATION IN INFORMATION  
TECHNOLOGY SYSTEMS



## **SCHEDULE FOR DELIVERABLES**

*Note: Days used in the table below refer to calendar days unless otherwise stated. Deliverables with due dates falling on a weekend or holiday shall be submitted the following Government work day after the weekend or holiday.*

Task	Deliverable ID	Deliverable Description
5.1.1	A	<b>Contractor Project Management Plan</b> Ten (10) days after receipt of order (ARO) and updated monthly thereafter. Electronic submission to: VA PM, COR, CO. Inspection: destination Acceptance: destination
5.1.2	A	<b>Monthly Performance Report</b> 5 <sup>th</sup> Business day of each calendar month, representing the prior WAM details for the prior calendar month. Electronic submission to: VA PM, COR, CO. Inspection: destination Acceptance: destination
5.1.3	A	<b>Kickoff Agenda</b> Five (5) calendar days prior to Kickoff Meeting occurrence. Electronic submission to: VA PM, COR, CO. Inspection: destination Acceptance: destination
5.1.3	B	<b>Kickoff Meeting Minutes</b> Three (3) business days after Kickoff Meeting occurrence. Electronic submission to: VA PM, COR, CO. Inspection: destination Acceptance: destination
5.2.1	A	<b>Study Package</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination



Task	Deliverable ID	Deliverable Description
5.2.1	B	<b>Clinical Study Package</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.2.2	A	<b>Study Package</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.2.2	B	<b>Clinical Study Package</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.2.3	A	<b>Study Package</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.2.3	B	<b>Clinical Study Package</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.3	A	<b>Study Preparation</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.3	B	<b>Study Recordings</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination

Task	Deliverable ID	Deliverable Description
5.3	C	<b>Data Analysis</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.3	D	<b>Report Generation</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.3	E	<b>Technical Editing</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.3	F	<b>Logistics Planning</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.3	G	<b>Study Disposition</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.3	H	<b>Study Review</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.3	I	<b>Study Publication and Presentation</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination

Task	Deliverable ID	Deliverable Description
5.3	J	<b>Design Materials</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.3	K	<b>Study Kick-off and FPE</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.4	A	<b>UX Guide Content</b> As agreed, following the completed activity, with interim submissions to the Effort Tracker Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination
5.4	B	<b>UX Guide Report</b> Due the last Monday of each month Electronic submission to: VA PM, COR, CO Inspection: destination Acceptance: destination