

Exhibit 300 (BY2008)

PART ONE	
OVERVIEW	
1. Date of Submission:	2007-02-05
2. Agency:	009
3. Bureau:	25
4. Investment Name:	NIH CC Clinical Research Information System (CRIS)
5. UPI:	009-25-01-06-01-3006-00
6. What kind of investment will this be in FY2008?	
Operations and Maintenance	
7. What was the first budget year this investment was submitted to OMB?	
FY2002	
8. Provide a brief summary and justification for this investment, including a brief description of how this closes in part or in whole an identified agency performance gap.	
<p>The Clinical Research Information System (CRIS) was designed and implemented to support medical care and research support at the NIH Clinical Center. As the nation's largest research hospital, data collection and analysis for clinical trials is critical to improving the health of the nation. The CRIS supports over 1200 clinical trials at the hospital for the NIH through an enterprise of interfaced applications. As CRIS enters the O & M phase, the vision of multiple interfaced COTS systems is almost complete: The modules currently in production include: The hospital information core, radiology, nutrition, surgery, scheduling and admissions, Lab, transfusion medicine and EKG systems The Pharmacy system and a clinical data mart are the final modules scheduled for the project. Replacing a 25 year old legacy system, CRIS now offers a central source of data, images and reports for clinical researchers of the NIH intramural program. The project has mitigated the manual transfer of data, and has created electronic access to clinical and research data. The CRIS has been developed to meet multiple goals of the PMA. The key PMA is the e-government initiative. Clinical and research data including images are now ordered, documented and stored electronically. This has been critical to sustaining the research enterprise at the NIH, and allowed researchers access to larger datasets than in the past. A second PMA goal of human capital is also been addressed with this project. With the nursing shortage and decreased funding, there is decreased staffing. Therefore, the clinical care areas require efficient data capture into a system that accrues data once for care and for research. The CRIS system has reduced time for M.D.'s to enter orders (see performance measures) and also to make care decisions. This system has increased employee satisfaction with an electronic medical record system (see performance measures). The last PMA is R & D investment criteria. The core mission of the NIH is research. CRIS has enabled the intramural program to pool all patient data into one repository creating efficiencies and allowing researchers to analyze increasingly more complex data and results by protocol or across protocols. CRIS continues to meet goals set through a rigorous CPIC process. Budget requests are vetted through the project Steering Committee, the NIH IT Working Group, and evaluated through the NIH Budget and Management Working Group.</p>	
9. Did the Agency's Executive/Investment Committee approve this request?	
yes	
9.a. If "yes," what was the date of this approval?	
2006-06-23	
10. Did the Project Manager review this Exhibit?	
yes	
12. Has the agency developed and/or promoted cost effective, energy-efficient and environmentally sustainable techniques or practices for this project.	
no	
12.a. Will this investment include electronic assets (including computers)?	
yes	
12.b. Is this investment for new construction or major retrofit of a Federal building or facility? (answer applicable to non-IT assets only)	
no	
13. Does this investment support one of the PMA initiatives?	

yes	
If yes, select the initiatives that apply:	
Expanded E-Government	
Human Capital	
R and D Investment Criteria	
13.a. Briefly describe how this asset directly supports the identified initiative(s)?	
CRIS supports the NIH electronic patient & research record. The PMA e-government initiative is supported directly with the creation of an electronic medical record and the creation of standardized databases that will be Interoperable with other medical information systems and allow for data-sharing across government & private health care providers.	
14. Does this investment support a program assessed using OMB's Program Assessment Rating Tool (PART)?	
yes	
14.a. If yes, does this investment address a weakness found during the PART review?	
no	
14.b. If yes, what is the name of the PART program assessed by OMB's Program Assessment Rating Tool?	
2007: NIH - Intramural Research	
14.c. If yes, what PART rating did it receive?	
Effective	
15. Is this investment for information technology (See section 53 for definition)?	
yes	
16. What is the level of the IT Project (per CIO Council's PM Guidance)?	
Level 2	
17. What project management qualifications does the Project Manager have? (per CIO Council's PM Guidance)	
(1) Project manager has been validated as qualified for this investment	
18. Is this investment identified as high risk on the Q4 - FY 2006 agency high risk report (per OMB's high risk memo)?	
no	
19. Is this a financial management system?	
no	
19.a. If yes, does this investment address a FFIA compliance area?	
no	
19.a.1. If yes, which compliance area:	
Not Applicable	
20. What is the percentage breakout for the total FY2008 funding request for the following? (This should total 100%)	
Hardware	0
Software	40
Services	60
21. If this project produces information dissemination products for the public, are these products published to the Internet in conformance with OMB Memorandum 05-04 and included in your agency inventory, schedules and priorities?	
n/a	
22. Contact information of individual responsible for privacy related questions.	
Name	
Karen Pla	
Phone Number	
301-402-6201	
Title	

NIH Privacy Act Officer

Email

plak@mail.nih.gov

23. Are the records produced by this investment appropriately scheduled with the National Archives and Records Administration's approval?

yes

SUMMARY OF SPEND

1. Provide the total estimated life-cycle cost for this investment by completing the following table. All amounts represent budget authority in millions, and are rounded to three decimal places. Federal personnel costs should be included only in the row designated Government FTE Cost, and should be excluded from the amounts shown for Planning, Full Acquisition, and Operation/Maintenance. The total estimated annual cost of the investment is the sum of costs for Planning, Full Acquisition, and Operation/Maintenance. For Federal buildings and facilities, life-cycle costs should include long term energy, environmental, decommissioning, and/or restoration costs. The costs associated with the entire life-cycle of the investment should be included in this report.

All amounts represent Budget Authority

(Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions)

	PY-1 & Earlier	PY	CY	BY
	-2005	2006	2007	2008
Planning Budgetary Resources	4.180	0.000	0.000	0.000
Acquisition Budgetary Resources	49.428	6.056	0.000	0.000
Maintenance Budgetary Resources	2.773	1.552	6.500	7.135
Government FTE Cost	8.350	4.110	4.270	4.440
# of FTEs	48	50	53	53

Note: For the cross-agency investments, this table should include all funding (both managing partner and partner agencies).

Government FTE Costs should not be included as part of the TOTAL represented.

2. Will this project require the agency to hire additional FTE's?

no

3. If the summary of spending has changed from the FY2007 President's budget request, briefly explain those changes.

Changed because budget was cut.

PERFORMANCE

In order to successfully address this area of the exhibit 300, performance goals must be provided for the agency and be linked to the annual performance plan. The investment must discuss the agency's mission and strategic goals, and performance measures must be provided. These goals need to map to the gap in the agency's strategic goals and objectives this investment is designed to fill. They are the internal and external performance benefits this investment is expected to deliver to the agency (e.g., improve efficiency by 60 percent, increase citizen participation by 300 percent a year to achieve an overall citizen participation rate of 75 percent by FY 2xxx, etc.). The goals must be clearly measurable investment outcomes, and if applicable, investment outputs. They do not include the completion date of the module, milestones, or investment, or general goals, such as, significant, better, improved that do not have a quantitative or qualitative measure.

Agencies must use Table 1 below for reporting performance goals and measures for all non-IT investments and for existing IT investments that were initiated prior to FY 2005. The table can be extended to include measures for years beyond FY 2006.

Table 1

Fiscal Year	Strategic Goal(s) Supported	Performance Measure	Actual/baseline (from Previous Year)	Planned Performance Metric (Target)	Performance Metric Results (Actual)
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1	2004	DHHS Goal 5: Improve the Quality of Healthcare Services	Percentage of medical orders entered by authorized prescriber.	55% of medical orders entered electronically by authorized prescriber	60% of medical orders will be entered by authorized prescriber	62% of all orders entered by medical provider, 88% of medications orders entered by medical provider. Represents an increase of 16% over baseline for all medical orders.
2	2004	DHHS Goal 8: Achieve excellence in management practices	Schedule Variance/Cost Variance	Cost Variance = 0/Schedule Variance = 0	Schedule/Cost Variance less than 10%	Schedule Variance = - 8.61, cost variance = .82
3	2004	DHHS Goal 4: Enhance the capacity and productivity of the Nation's health science research enterprise	Percent of valid signed protocol consents posted in the medical record	As of FY 03, 84% of valid signed protocol consents are posted in the medical record	84.5%	85% of signed protocol consents are posted in the medical record
4	2004	DHHS Goal 5: Improve the Quality of Healthcare Services	Mean medical order time in minutes	Mean Medical order set completion time in legacy system is 40.22 min +/- 13.42 min in July 2003	38 +/- 10 minutes	Mean medical order time in CRIS was 34.11 minutes +/- 8.14 min.
5	2005	DHHS Goal 5: Improve the quality of health care services	Percentage of medical orders entered electronically by prescriber	62% of medical orders entered electronically by authorized prescriber	65%	66.3% of all medical orders now entered electronically by medical provider, 88% of medication orders entered electronically by medical care provider
6	2005	DHHS Goal 5: Improve the quality of health care services	Likert Scale - Usefulness, ease of use, supports clinical care and research	Likert Scale results (7 point scale) with legacy system: Usefulness - 4.3; Ease of Use - 3.65; Supports Clinical Care - 4.86; Supports Clinical Research - 4.38	Electronic user satisfaction survey will be administered 3 months post go-live and then one-year post go-live	At three months post go-live, data on satisfaction reflects systems issues with printing. Survey will be administered after implementation is complete.
7	2005	DHHS Goal 5: Improve the Quality of Healthcare Services	Percentage of users satisfied with system training	None for new system	90%	94% of users were satisfied with training. This included measures for satisfaction with methods, directions, content, testing, questions, environment and confidence in using the system post training.
8	2005	DHHS Goal 5: Improve the Quality of Healthcare Services	Patient wait time	18 minutes	10 minutes	Prior to CRIS, patients waited an average of 18 minutes for phlebotomy services as paper orders were

						interpreted and entered into the computer. Use of electronic orders has decreased patient wait times to 4-5 minutes.
9	2006	See Table 2 for subsequent years	See Table 2 for subsequent years	See Table 2 for subsequent years	See Table 2 for subsequent years	See Table 2 for subsequent years

All new IT investments initiated for FY 2005 and beyond must use Table 2 and are required to use the FEA Performance Reference Model (PRM). Please use Table 2 and the PRM to identify the performance information pertaining to this major IT investment. Map all Measurement Indicators to the corresponding "Measurement Area" and "Measurement Grouping" identified in the PRM. There should be at least one Measurement Indicator for at least four different Measurement Areas (for each fiscal year). The PRM is available at www.egov.gov.

Table 2

	Fiscal Year	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Planned Improvement to the Baseline	Actual Results
1	2006	Customer Results	Service Efficiency	Prescriber electronic order entry time	05 results - 34.11 min +/- 8.14 minutes	29 minutes	Multiple order entry took 21.2 minutes, entry of same orders using order sets took 15.5 minutes, a decrease of 27%. Demonstrated efficiencies in creating order sets for patient care and research.
2	2006	Processes and Activities	Errors	Number of missing lab specib specimens	Lost or missing lab specimens - 52 per year	39 less missing specimens	Decreased from 52 to 21 lost or mislabeled specimens, a decrease of 60%
3	2006	Mission and Business Results	Health Care Research and Practitioner Education	Perceived Usefulness, Perceived Ease of Use , Support of Clinical Care, Support Research, Customer Support, Training Satisfaction	Perceived usefulness - 52 %, Perceived Ease of Use 46%, Support of Clinical Care - 74%, Support Research 74%, Customer Support - 75%, Training satisfaction - 94%	Improve user satisfaction and ease of use of the medical information system by 10%	Perceived Usefulness - 73% (up 21%), Perceived Ease of Use - 57% (Up 11%), Support of Clinical Care - 85% (Increased 11%), Support Research - 78% (increased 4%), Customer Support - 85% (increased 10%), Training Satisfaction - 96% (increased

							2%)
4	2006	Technology	Interoperability	Number of interface systems	At beginning of project had 5 interfaced systems	6	Built and interfaced scheduling system, surgery system, ADT system
5	2007	Processes and Activities	Errors	Percentage use of physician order entry	05 results - 66.3 % of all orders	70%	TBD
6	2007	Customer Results	Automation	Number of protocol order sets	Count of protocol order sets	Increase number of order sets by 10%	TBD
7	2007	Mission and Business Results	Health Care Research and Practitioner Education	Perceived Usefulness, Perceived Ease of Use , Support of Clinical Care, Support Research, Customer Support, Training Satisfaction	Perceived usefulness - 73%, Perceived Ease of use - 57%, Support of Clinical Care - 85%, Support of Research - 78%, Customer Support - 85%, Training Satisfaction - 96%.	Increase user satisfaction with system across all measures by 5%	TBD
8	2007	Technology	Interoperability	Number of interface systems	5	6	TBD

EA

In order to successfully address this area of the business case and capital asset plan you must ensure the investment is included in the agency's EA and Capital Planning and Investment Control (CPIC) process, and is mapped to and supports the FEA. You must also ensure the business case demonstrates the relationship between the investment and the business, performance, data, services, application, and technology layers of the agency's EA.

1. Is this investment included in your agency's target enterprise architecture?

yes

2. Is this investment included in the agency's EA Transition Strategy?

yes

2.a. If yes, provide the investment name as identified in the Transition Strategy provided in the agency's most recent annual EA Assessment.

NIH CRIS - Clinical Research Information System

3. Identify the service components funded by this major IT investment (e.g., knowledge management, content management, customer relationship management, etc.). Provide this information in the format of the following table. For detailed guidance regarding components, please refer to <http://www.whitehouse.gov/omb/egov/>.

Component: Use existing SRM Components or identify as NEW. A NEW component is one not already identified as a service component in the FEA SRM.

Reused Name and UPI: A reused component is one being funded by another investment, but being used by this investment. Rather than answer yes or no, identify the reused service component funded by the other investment and identify the other investment using the Unique Project Identifier (UPI) code from the OMB Ex 300 or Ex 53 submission.

Internal or External Reuse?: Internal reuse is within an agency. For example, one agency within a department is reusing a service component provided by another agency within the same department. External reuse is one agency within a department reusing a service component

provided by another agency in another department. A good example of this is an E-Gov initiative service being reused by multiple organizations across the federal government.

Funding Percentage: Please provide the percentage of the BY requested funding amount used for each service component listed in the table. If external, provide the funding level transferred to another agency to pay for the service.

	Agency Component Name	Agency Component Description	Service Type	Component	Reused Component Name	Reused UPI	Internal or External Reuse?	Funding %
1	Remedy / TeamTrack	Statistical management of quality uses shared infrastructure tools.	Management of Processes	Quality Management	Quality Management	009-25-02-00-01-3109-00	Internal	3
2	Email	Information on general coordination and communication not related to patient-specific issues or data is received through the shared email infrastructure.	Routing and Scheduling	Inbound Correspondence Management	Inbound Correspondence Management	009-25-02-00-01-3109-00	Internal	0
3	CRIS Enterprise	The process of protocol implementation and care sequencing is controlled by flowsheets within Sunrise Clinical Manager and protocols provided by the research community.	Tracking and Workflow	Process Tracking	Process Tracking		No Reuse	8
4	Email	Information for coordination and communication not related to patient-specific issues or data is transmitted through shared email infrastructure.	Routing and Scheduling	Outbound Correspondence Management	Outbound Correspondence Management	009-25-02-00-01-3109-00	Internal	0
5	CRIS Enterprise	Patient and test information will be mapped to protocols performed and results obtained through ancillary	Knowledge Management	Information Mapping / Taxonomy	Information Mapping / Taxonomy		No Reuse	9

		systems.						
6	Documentation	Shared disk volumes support a CRIS-wide repository of system documentation with supervised access.	Knowledge Management	Information Sharing	Information Sharing	009-25-02-00-01-3109-00	Internal	5
7	CRIS Enterprise	CRIS data will be categorized based on complaint, diagnosis, protocol, demographic, and result information.	Knowledge Management	Categorization	Categorization		No Reuse	4
8	Storage	CRIS core application stores all transactions related to medical orders, clinical documentation and result for clinical care using enterprise storage facilities.	Knowledge Management	Knowledge Distribution and Delivery	Knowledge Distribution and Delivery	009-25-02-00-01-3109-00	Internal	6
9	CRIS Enterprise	The CRIS system will organize documentation and classify by source for email, fax, paper, and electronic formats.	Records Management	Document Classification	Document Classification		No Reuse	4
10	CRIS Enterprise	The CRIS core system supports advanced analytical graphics for research analysis.	Visualization	Graphing / Charting	Graphing / Charting		No Reuse	3
11	Custom Reports	The CRIS core system supports ad-hoc reporting of clinical and protocol data using enterprise tools.	Reporting	Ad Hoc	Ad Hoc	009-25-02-00-01-3109-00	Internal	3
12	CRIS Enterprise	The CRIS system provides a wide variety of reports for	Reporting	Standardized / Canned	Standardized / Canned		No Reuse	5

		patient and protocol management.						
13	CITRIX / Casper	Access to CRIS user interface functions and support functions is provided through enterprise remote secure connection facilities.	Systems Management	Remote Systems Control	Remote Systems Control	009-25-02-00-01-3109-00	Internal	2
14	Remedy / TeamTrack	Configuration control and user issue resolution tracking are supported by common infrastructure tools.	Systems Management	Issue Tracking	Issue Tracking	009-25-02-00-01-3109-00	Internal	9
15	Security	Common security tools are used for intrusion prevention and detection, certificate management and distribution, and centralized authentication and authorization.	Security Management	Intrusion Prevention	Intrusion Prevention	009-25-02-00-01-3109-00	Internal	4
16	CRIS Enterprise	The Sunrise Clinical Manager application server incorporates QDX Integrator for communication with and control of other applications.	Development and Integration	Enterprise Application Integration	Enterprise Application Integration		No Reuse	9
17	Internet Explorer	The use of remote interfaces allows CRIS to leverage the use of browsers to support NIH-wide access to the application.	Knowledge Management	Information Retrieval	Information Retrieval	001-25-02-00-01-3109-00	Internal	2
18	NIHlogin	NIH has implemented a shared single-	Security Management	Identification and Authentication	Identification and Authentication	001-25-02-00-01-	Internal	1

		signon service that can be leveraged across NIH systems.				3109-00		
19	NIHnet	NIH provides a centralized network backbone that is widely leveraged across NIH to support data communications	Organizational Management	Network Management	Network Management	001-25-02-00-01-3109-00	Internal	3
20	PVCS	CRIS shares a common configuration management tool and methodology with other Clinical Center projects and systems.	Management of Processes	Configuration Management	Configuration Management	009-25-02-00-01-3109-00	Internal	4
21	Sybase	A Clinical Research Data Warehouse will provide information on trials and results to the research community.	Data Management	Data Warehouse	Data Warehouse		No Reuse	9
22	CRIS Enterprise	While sharing network and management infrastructure, CRIS maintains its own servers for application integrity and security.	Asset / Materials Management	Computers / Automation Management	Computers / Automation Management		No Reuse	2
23	NIHLogin	Digital certificate and signature infrastructure is re-used through the NIH infrastructure.	Security Management	Digital Signature Management	Digital Signature Management	001-25-02-00-01-3109-00	Internal	0
24	CRIS Enterprise	Sunrise Clinical Manager enforces and manages business rules for Clinical Center task sequencing and control.	Management of Processes	Business Rule Management	Business Rule Management		No Reuse	2
25	CRIS Enterprise	QDX Integrator provides data and control	Development and Integration	Data Integration	Data Integration		No Reuse	2

		message interchange with ancillary applications to provide the CRIS user community with an integrated application.						
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4. To demonstrate how this major IT investment aligns with the FEA Technical Reference Model (TRM), please list the Service Areas, Categories, Standards, and Service Specifications supporting this IT investment.

FEA SRM Component: Service Components identified in the previous question should be entered in this column. Please enter multiple rows for FEA SRM Components supported by multiple TRM Service Specifications.

Service Specification: In the Service Specification field, Agencies should provide information on the specified technical standard or vendor product mapped to the FEA TRM Service Standard, including model or version numbers, as appropriate.

	SRM Component	Service Area	Service Category	Service Standard	Service Specification (i.e., vendor and product name)
1	Information Retrieval	Service Access and Delivery	Access Channels	Web Browser	Internet Explorer
2	Remote Systems Control	Service Access and Delivery	Access Channels	Wireless / PDA	802.11x
3	Network Management	Service Access and Delivery	Delivery Channels	Virtual Private Network (VPN)	Cisco Systems VPN3000 Concentrator
4	Network Management	Service Access and Delivery	Delivery Channels	Internet	HTTP, HTTPS
5	Network Management	Service Access and Delivery	Delivery Channels	Intranet	HTTP, HTTPS, SSL
6	Identification and Authentication	Service Access and Delivery	Service Requirements	Authentication / Single Sign-on	Active Directory, Citrix
7	Identification and Authentication	Service Access and Delivery	Service Requirements	Legislative / Compliance	SecurID 2-factor Authentication, FISMA
8	Remote Systems Control	Service Platform and Infrastructure	Support Platforms	Wireless / Mobile	802.11x
9	Enterprise Application Integration	Service Platform and Infrastructure	Support Platforms	Platform Independent	J2EE
10	Enterprise Application Integration	Service Platform and Infrastructure	Support Platforms	Platform Dependent	.NET
11	Enterprise Application Integration	Service Platform and Infrastructure	Delivery Servers	Web Servers	Microsoft IIS, Apache, Orion
12	Enterprise Application Integration	Service Platform and Infrastructure	Delivery Servers	Application Servers	Eclipsys Sunrise Clinical Manager
13	Enterprise Application Integration	Service Platform and Infrastructure	Software Engineering	Integrated Development Environment	Microsoft Visual Studio, Merant Collage
14	Configuration Management	Service Platform and Infrastructure	Software Engineering	Software Configuration Management	PVCS
15	Quality Management	Service Platform and Infrastructure	Software Engineering	Test Management	Serena TeamTrack

16	Data Warehouse	Service Platform and Infrastructure	Database / Storage	Database	Microsoft SQL Server, Sybase, 4D
17	Data Warehouse	Service Platform and Infrastructure	Database / Storage	Storage	NAS, SAN
18	Computers / Automation Management	Service Platform and Infrastructure	Hardware / Infrastructure	Servers / Computers	Windows/Intel, Sun, IBM RISC
19	Document Classification	Component Framework	Data Interchange	Data Exchange	Eclipsys Sunrise Clinical Manager
20	Computers / Automation Management	Service Platform and Infrastructure	Hardware / Infrastructure	Peripherals	USB, IEEE-1284
21	Network Management	Service Platform and Infrastructure	Hardware / Infrastructure	Wide Area Network (WAN)	TCP/IP, PoS
22	Network Management	Service Platform and Infrastructure	Hardware / Infrastructure	Local Area Network (LAN)	TCP/IP
23	Network Management	Service Platform and Infrastructure	Hardware / Infrastructure	Network Devices / Standards	SNMP, CA Unicenter
24	Digital Signature Management	Component Framework	Security	Certificates / Digital Signatures	FIPS 182-2, FIPS 140-2, NIST Guidance
25	Business Rule Management	Component Framework	Business Logic	Platform Dependent	Eclipsys Sunrise Clinical Manager
26	Enterprise Application Integration	Component Framework	Data Management	Database Connectivity	ODBC
27	Ad Hoc	Component Framework	Data Management	Reporting and Analysis	Crystal Reports
28	Enterprise Application Integration	Service Interface and Integration	Integration	Middleware	QDX Integrator
29	Enterprise Application Integration	Service Interface and Integration	Integration	Enterprise Application Integration	QDX Integrator
30	Data Integration	Service Interface and Integration	Interoperability	Data Format / Classification	QDX Integrator, HL7, Microsoft MSMQ
31	Inbound Correspondence Management	Service Access and Delivery	Access Channels	Collaboration / Communications	Microsoft Exchange
32	Outbound Correspondence Management	Service Access and Delivery	Access Channels	Collaboration / Communications	Microsoft Exchange
33	Issue Tracking	Service Platform and Infrastructure	Software Engineering	Software Configuration Management	Serena Teamtrack, Remedy
34	Intrusion Prevention	Service Platform and Infrastructure	Hardware / Infrastructure	Network Devices / Standards	Firewall, SecurID
35	Information Sharing	Service Platform and Infrastructure	Database / Storage	Storage	SAN shared volume
36	Knowledge Distribution and Delivery	Service Platform and Infrastructure	Database / Storage	Storage	SAN shared volume
37	Process Tracking	Component Framework	Business Logic	Platform Dependent	Eclipsys Sunrise Clinical Manager
38	Information Mapping /	Service Interface	Interoperability	Data Transformation	Eclipsys Sunrise Clinical

	Taxonomy	and Integration			Manager, QDX Integrator
39	Categorization	Service Interface and Integration	Interoperability	Data Format / Classification	Eclipsys Sunrise Clinical Manager
40	Standardized / Canned	Component Framework	Data Management	Reporting and Analysis	Eclipsys Sunrise Clinical Manager
41	Graphing / Charting	Component Framework	Data Management	Reporting and Analysis	Eclipsys Sunrise Clinical Manager

5. Will the application leverage existing components and/or applications across the Government (i.e., FirstGov, Pay.Gov, etc)?

no

5.a. If yes, please describe.

No. However information will be used to supplement the information found at ClinicalTrials.gov

6. Does this investment provide the public with access to a government automated information system?

no

PART THREE

RISK

You should perform a risk assessment during the early planning and initial concept phase of the investment's life-cycle, develop a risk-adjusted life-cycle cost estimate and a plan to eliminate, mitigate or manage risk, and be actively managing risk throughout the investment's life-cycle.

Answer the following questions to describe how you are managing investment risks.

1. Does the investment have a Risk Management Plan?

yes

1.a. If yes, what is the date of the plan?

2006-06-01

1.b. Has the Risk Management Plan been significantly changed since last year's submission to OMB?

no

COST & SCHEDULE

1. Was operational analysis conducted?

yes

1.a. If yes, provide the date the analysis was completed.

2006-12-31

What were the results of your operational analysis?

In August 2004, DCRI and CSC jointly performed an Operational Readiness Review prior to the original go-live for CRIS CORE. In addition, before each of the ancillary go-lives, or Eclipsys upgrades, an Operational Readiness Review is also performed. This review typically consists of a checklist of readiness objectives that need to be achieved before the system go live, responsible staff member, date, etc. An Operational Analysis will be performed for the entire system each year covering costs, schedule and performance as requested by NIH management (the IT Working Group).