Office of the National Coordinator for Health Information Technology
Department of Health and Human Services

American Recovery and Reinvestment Act of 2009
Immediate Funding to Strengthen the Health Information Technology Infrastructure:
Strategic Health IT Advanced Research Projects (SHARP)

Program Guidance
Funding Opportunity Announcement
Fiscal Year 2010

Application Due Date: January 25, 2010
Release Date:

Legislative Authority: Section 3011 of the Public Health Service Act (PHSA), as added by the American Recovery and Reinvestment Act of 2009 (Recovery Act), Division A – Appropriations Provisions

Executive Summary

This funding opportunity is for four cooperative agreements to be funded under section 3011 of the Public Health Service Act, as added by the American Recovery and Reinvestment Act of 2009 (Recovery Act), Public Law 111-5. The purpose of the Strategic Health IT Advanced Research Project awards is to fund research focused on achieving breakthrough advances that are needed to address well-documented problems that have impeded the adoption of health IT. The research will also accelerate progress towards achieving nationwide meaningful use of health information technology in support of a high-performing, learning health care system.

On February 17, 2009, the President signed the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act). This statute includes provisions in Title XIII of Division A, and Title IV of Division B that together may be cited as the "Health Information Technology for Economic and Clinical Health Act of 2009" or the "HITECH Act". The HITECH Act authorizes unprecedented investments in advancing the appropriate use of health IT to improve the quality of health care for each individual in the United States. Of these investments, $60,000,000 will support approximately four cooperative agreements under this funding opportunity. These awards will offer one-time funding for a four-year project period.

As this funding opportunity is supported by Recovery Act funds, as described below, additional financial and performance reporting requirements will be associated with it.

American Recovery and Reinvestment Act of 2009
Strategic Health IT Advanced Research Projects

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Program Office:
Department of Health and Human Services (HHS)
Office of the National Coordinator for Health Information Technology (ONC)

Funding Opportunity Title: American Recovery and Reinvestment Act of 2009, Health Information Strategic Health IT Advanced Research Projects

Announcement Type: New Competitive Program

Funding Opportunity Number: HHS-2010-ONC-TR-005

Catalog of Federal Domestic Assistance (CFDA) Number: 93.728

Key Dates and Submission Information: A technical assistance session is expected to be held on December 21, 2009. Applicants are requested, but not required, to submit a letter of intent by 11:59 p.m., Eastern Time, on January 4, 2010. The deadline date for submission of applications is 11:59 p.m., Eastern Time, on January 25, 2010. Applications will then undergo an objective review. Successful applications will result in the award of four-year cooperative agreements. Awards for the Strategic Health IT Advanced Research Projects are anticipated to be made by March 15, 2010.

Approximate Funding	FOA Released	Letters of Intent Due	Applications Due	Estimated Cooperative Agreements Awarded	Anticipated Start Date
$60 million	December [XX], 2009	January 4, 2010 11:59 PM EST Wil.Yu@HHS.gov	January 25, 2010 11:59 PM EST http://www.grants.gov	March 15,2010	April 1, 2010

I. FUNDING OPPORTUNITY DESCRIPTION

1. Statutory Authority

The statutory authority for this program is contained in Public Health Service Act (PHSA) Sec. 3011, as added by the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act). As detailed in Appendix A, awards under Section 3011 are also subject to paragraphs (a) and (b) of PHSA Section 3017, as added by the Recovery Act.

2. Background

On February 17, 2009, the President signed the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act). This statute includes provisions in Title XIII of Division A, and Title IV of Division B that together may be cited as the "Health Information Technology for Economic and Clinical Health Act of 2009" or the "HITECH Act". The HITECH Act authorizes unprecedented investments in advancing the appropriate use of health information technology (health IT) to improve quality of care for each individual in the United States. Among the programs authorized by the HITECH Act are Medicare and Medicaid incentives to eligible professionals and hospitals for meaningful use of certified electronic health record (EHR) technology.

In 2009, the Health IT Policy Committee, a federal advisory committee established pursuant to PHSA Section 3002(a), as added by the Recovery Act, provided the National Coordinator with recommendations pertaining to an initial definition of meaningful use that focuses on major health care priorities and objectives and that would allow health providers to demonstrate that they are EHR technology in a meaningful way. (A collection of the Health IT Policy Committee's Meaningful Use documents, including the August 20th update, may be found at: http://healthit.hhs.gov/meaningfuluse).

The Health IT Policy Committee has recognized that achieving the ultimate goals of meaningful use will take a number of years, and that numerous tools and techniques will be necessary to overcome existing adoption barriers and attain meaningful use objectives over the longer-term. Incremental progress has been and continues to be made with regard to these challenges, and many existing federal and private sector research programs make valuable contributions addressing these challenges. These programs, however, are not specifically focused or resourced to achieve the accelerated adoption of health IT contemplated under the HITECH Act.

A more robust research infrastructure is critical to closing the gap between the promise of health IT and its realized benefits—including its direct contributions to achieving the goal of a transformed health care delivery system. The research infrastructure must be specifically designed and dedicated to supporting the goals of HITECH and overcoming health IT challenges to adoption and meaningful use.

This program will enhance the research infrastructure so that it furnishes robust support for key health IT activities including:

- Exploring and defining fundamental research questions within an identified set of high-priority areas; answers to these research questions will address barriers to the nationwide electronic exchange and use of health information in a secure, private, and accurate manner;
- Providing opportunities for relevant academic and industrial researchers, health IT developers and implementers, health care providers and delivery system researchers, and other stakeholders to collaborate for the purpose of stimulating innovation and translating incorporating the results of research into health IT products;

- Creating breakthrough solutions, technologies, and services, which may be applied in health IT in the near- and long-term, and which address identified challenges and opportunities relevant to the adoption and meaningful use of health IT;
- Identifying a range of model (proof-of-concept) systems that serve as motivating and unifying forces to drive fundamental research in health IT; and
- Encouraging effective use of health IT through rapid dissemination of research results, findings on innovations and novel tools, to developers and purchasers of health IT.

Taken together, these activities will significantly enhance the performance of health IT solutions in support of the goals outlined in the strategic plan developed by the National Coordinator pursuant to PHSA Section 3001(c)(3), as added by the Recovery Act, including the nationwide achievement of meaningful use of health IT by all providers.

3. Purpose

These research projects will focus on solving current and expected future challenges that represent barriers to adoption and meaningful use of health IT, through the proliferation of new methods and advanced technologies. These projects focus on areas where "breakthrough" advances are needed. For example, potential security breaches represent a major threat to public trust in the electronic maintenance and exchange of health information. Research would identify new methods to create tools that will, through their incorporation into deployed technology, enhance data security. In doing so, the program will, in critical areas, close the gap between the promise of health IT and its realized benefits. The projects will be specifically designed and dedicated to supporting the goals of HITECH and overcoming health IT challenges to adoption and meaningful use. Research areas requiring breakthrough product solutions include:

- Security functions, policies and technology tools facilitating increasingly widespread, rapid, and sophisticated, electronic use and exchange of health information while assuring and enhancing individuals' safety and privacy.
- Clinician interactions with patient models and abstractions that efficiently place data into context and synthesize them with medical knowledge in ways that make clinical sense for that patient
- Modular and flexible architectures enabling healthcare data liquidity between multiple healthcare stakeholders.
- Patient data accumulated, organized, and analyzed at public health and population levels to promote improved quality, safety and efficiency of care and extend public health and research.

This Funding Opportunity Announcement (FOA) will result in new competitively-awarded cooperative agreements to establish Strategic Health IT Advanced Research Projects (SHARP). Sites (or Awardees) under this program will conduct research focusing on where breakthrough advances are needed to address well-documented problems that have impeded adoption of health IT and to accelerate progress towards achieving nationwide meaningful use of health IT in support of a high-performing, learning health care system. The goal of these research efforts is to improve the process for adoption of HIT and providing a more efficient pathway towards meaningful use.

4. Project Approach

ONC expects to award four cooperative agreements to support establishment of Strategic Health IT Advanced Research Projects Sites for a project period of four years. Each Site (or Awardee) will have a

two-part mission:

> (1) to implement a collaborative, interdisciplinary program of research addressing a specific focus area from the list provided below, addressing short-term as well as long-term challenges; and
> (2) to develop and implement a cooperative program between researchers, patient groups, health care providers, and other health IT sector stakeholders to transition the results of research into practice.

Each Awardee will focus on areas where breakthrough improvements are needed to address problems that have impeded adoption of health IT and thereby accelerate progress on the pathway towards achieving the goals outlined in the strategic plan for health IT developed by the National Coordinator pursuant to PHSA Section 3001(c)(3) as added by the Recovery Act, specifically including the nationwide achievement of meaningful use of health IT to achieve transformational improvement of the health care system.

Each Awardee will implement a collaborative, inter-disciplinary research program addressing one of the specific focus area(s) listed in Section I, Part 4a, below. An eligible entity may, as described in Section IV (below), apply for funding in separate applications to establish more than one Site, and thus it is possible a single eligible entity ("institution") may receive more than one award under this program. Regardless of the total number of institutions funded to establish Sites under this program, it is expected that the all of the Sites will collaborate with each other, as there will be numerous points of intersection among the Sites' agendas.

4a. Research focus areas

In no particular order, the four foci for research identified below will be addressed by this program. The areas have been assigned numbers for ease of reference. While there are many research challenges associated with the promotion of health IT adoption, these four areas of focus were identified by HHS staff and advisers as critical areas of investigation, presenting both short-term and long-term opportunities for study and innovation. Appendix B provides further detail about each of these areas.

(1) **Security of Health Information Technology** – This research area addresses the challenges of developing security and risk mitigation policies and the technologies necessary to build and preserve the public trust as health IT systems become ubiquitous.

Health information security is a cornerstone of achieving nationwide exchange and use of electronic health information. Without security there can be no trust. Without trust, we cannot have successful health IT adoption or health information exchange. Without adoption and exchange we cannot achieve the improved health care and health outcomes we want and need. The nationwide achievement of transformational health care improvement through meaningful use of health IT will require the electronic storage and maintenance of an unprecedented volume of data by an unprecedented number of organizational entities. The major challenges requiring breakthrough product solutions include the development of security functions, policies and technology tools that will facilitate increasingly widespread, rapid, and sophisticated, electronic use and exchange of health information while assuring and enhancing individuals' safety and privacy.

This research area is responsive to paragraphs (1), (4), (5), and (6) of the PHSA 3011(a), as added by the Recovery Act, through the following activities:

- Promoting the development and implementation of health information technology solutions that will support the electronic exchange and use of health information in a secure, private manner;
- Promoting the development and implementation of technologies and best practices that enhance the protection of health information by all holders of individually identifiable health information;

- Enhancing the capabilities and functionalities of tools to support privacy and security of individually identifiable health information as it is exchanged and used; and,

- Supporting and enhancing the assurance of privacy needed providers' and patients' widespread acceptance of telemedicine and robust participation in clinical data repositories and registries.

Major topics for research could include:

- Data Integrity and Availability: Identity Management and Future-Proofing focusing on short- and long-term issues
- Data Confidentiality: modeling and simulation focusing on preventive measures
- Consumer access and control: addressing consumer concerns regarding timely access to their own data and how their health data is shared and, potentially, their perceived lack of consumer control
- Data Access: to only those who need access for care delivery;
- Data breaches
- Data stewardship and the ability to assure minimum necessary access and appropriate use of patient data.

Another key aspect of this research topic would be performance measurement and enforcement of policies and technology tools once they are developed which would include clear links between compliance and benefits.

The SHARP for security will need to address short- and long- term challenges. Short term focus is needed to help improve level of trust in health information data and long term focus is needed to sustain this progress.

(2) **Patient-Centered Cognitive Support** – This research area addresses the challenge of harnessing the power of health IT so that it integrates with, enhances and supports clinicians' reasoning and decision making, rather than forcing them into a mode of thinking that is natural to machines but not to people.

Integration with the delivery of care of appropriate health IT to facilitate high levels of clinical performance and effective decision-making poses great challenges for many reasons. Today's clinicians spend a great deal of time and energy searching and sifting through raw data about patients and trying to integrate these data with their general medical knowledge to create an accurate assessment of a patient's situation that is necessary to make patient-care decisions. Such sifting efforts force clinicians to devote precious time and cognitive resources to the details of data and make it more likely that they will overlook some important higher-order consideration. The health care IT systems of today tend to squeeze all cognitive support for the clinician through

the lens of health care transactions and the related raw data, without showing how data fit together and which elements are important or unimportant. As a result, an understanding of the patient can be lost amidst all the data, tests, and monitoring equipment. A highly-regarded 2009 study from the National Research Council (NRC) has identified many of these challenges and described the need for innovative approaches that represent significant points of departure from current practice. (See "Computational Technology for Effective Health Care: Immediate Steps and Strategic Directions," NRC, 2009). Research in this area will identify methods that transform large volumes of data into key elements of information and place in front of clinicians the most important information about that patient at that time, organized in ways that align with how clinicians think.

Major topics for research could include:

- Creating models that support dynamic abstraction of clinical information
- Techniques for parsimonious information display information that simplifies, while capturing essential features of a clinical decision problem
- Understanding decision making under stress and time pressure, and its implications for cognitive support
- Communication to clinicians, addressing message content and delivery, that blends with workflow
- Methods to support decisions that involve multiple stakeholders, taking into account their preferences and utilities
- Methods for minimizing and simplifying, when it is necessary, manual data input by clinicians

PHSA 3011(a), as added by the Recovery Act, directs the support of health IT architecture that will support the use of health information in an accurate manner. Additionally, paragraphs (3) and (5) of the same subsection of the statute authorize use of funding appropriated under PHSA Section 3018, as added by the Recovery Act, to disseminate training and information on best practices to integrate health IT into a provider's delivery of care, and to promote the use of clinical data repositories and registries. All of these paragraphs ((1), (3), and (5) of PHSA 3011(a) as added by the Recovery Act) point to longstanding challenges that require new and creative research related to the accurate and effective use of electronic health information to enhance the safety, quality, efficacy, and thus the overall value of care.

(3) **Healthcare Application and Network Platform Architectures** – This research area focuses on the development of new and improved architectures that will leverage benefits of today's architecture and focus on the flexibility and scalability needs for the future to address significant increase in capture, store and analysis of data. This research will improve upon current architectures by enabling greater application capability and flexibility, as well as a higher level of data service integration. It will support envisioned future development of the Nationwide Health Information Network (NHIN).

Health care is inherently a distributed, information-intensive enterprise. As the volume of data captured, stored, and used electronically increases, the nation will witness a concomitant increase in the need for architectures supporting applications and resources that can capture, store, and analyze that data. Historically, there has been a distinction between the applications and operating systems running on a computer, and the services and networks available through the internet. That distinction is increasingly artificial. People can now access the same data through multiple devices, across multiple platforms. Email, once only accessible through specialized applications running on a desktop machine, now can be used on mobile devices, through the web, on applications running on machines or through voicemail translation. Data liquidity in which

the data follows the patient requires application and network "liquidity" in which the applications and networks have similar flexibility. Standards-based, modular, flexible, and innovative architectures to provide healthcare providers, research, patients, and others with the data and application services that they need will be a key component of assuring that data liquidity is appropriately supported by application services. Research in this area will promote health IT adoption and meaningful use through the development of more flexible, modular, "swappable" tools that ensure that clinicians are using the best tool available to support their work.

PHSA 3011(a)(1), as added by the Recovery Act, authorizes support of health IT architecture that will support "the nationwide electronic exchange and use of health information in a secure, private, and accurate manner". This research focus specifically supports the development of new and improved architectures and technology infrastructure needed to achieve the goals outlined in the plan for health IT by the National Coordinator in support of PHSA 3001(c)(3), as added by the Recovery Act, and to support measures for determination of meaningful use of health IT by providers over time (required by Social Security Act (SSA) Sections 1848(o) and 1866(n), as added by Title IV in Division B of the Recovery Act).

We anticipate that this research can advance the field in three ways.

- **Network platforms for data analysis and services -** As we accumulate large amounts of data, having web-based services to capture, store and analyze data will be critical. Cloud computing, service-based architectures, and novel ways of integrating across wide area networks the flow and analysis of data will provide users with dynamic and configurable resources across the web, the grid, or the cloud.

  Major topics for research could include:
  - Dynamic assembly of services and resources, based on the nature of the data and the question being asked
  - Creation of architectural frameworks that can support a layered approach to managing data transport, semantics, and application services
  - Development of standards-based network services to support data capture, storage and analysis
  - Comparison of alternative architectures to support data capture, storage and analysis

- **Modular platforms for application development -** While network services provide a dynamic and configurable approach to large data services, there is a similar need for smaller-scale, but equally configurable and modular development platforms for users. Creating application building blocks that can be configured or assembled by a user to capture, store, and analyze data at a smaller scale will also be important.

  Major topics for research could include:
  - Configurable open-source platforms and development environments that will support modular software development
  - Development of standards-based, interoperable modules that can dynamically process and route data analysis functions

- **Integration of data services across the spectrum -** Although the scale of network platforms and application platforms are different, they both provide a modular approach to analyzing data. Ultimately, integration of application building blocks with the network building blocks provide an innovative platform in which the location or platform of the analysis is not important. Users will chose the right application for the thing that it does, rather than for the location on the web,

the ability to run on a particular operating system, computer, or mobile device. In this scenario, not only does the data follow the patient, but the applications and services do as well.

Major topics for research could include:

- Use of existing standards (or identification of new standards) for interoperability between data services
- Demonstration and evaluation of multi-tiered analysis platforms
- Object-oriented services for data and applications that integrate and organize data (and services) around patient needs

(4) **Secondary Use of EHR Data** – This research area focuses on strategies to enhance the use of health IT in improving the overall quality of health care.

Widespread implementation of EHRs and related health IT will result in the steady accumulation of large amounts of patient data that can be leveraged to improve the quality, safety and efficiency of care and extend public health and research. EHR data can be analyzed by providers, health plan and governments to identify best care practices and assess quality of care according to those practices. EHR data can also be applied to determine the relative clinical effectiveness of different interventions, *e.g.*, medications, devices and procedures. EHR data may be used to determine if medications or devices are posing post-market risks to patients. Finally, EHR data can be used to accelerate clinical research; for example, by serving as a source of phenotype data in genome association studies. As important as the potential applications are, and as straightforward as they may seem, several challenges requiring breakthrough solutions confront each of these uses. The challenges requiring breakthrough solutions include methods for addressing incomplete and inconsistent data and for extracting coded data from unstructured text. Research in this area will promote health IT adoption and meaningful use through new methods that place greatly improved computational and analytical tools in the hands of researchers and practitioners.

Major topics for research could include:

- Strategies, heuristics and methods to compensate for inconsistent, conflicting and incomplete data
- Methods for retrospectively and prospectively creating "in silico" cohorts of study controls and intervention populations
- Technical approaches and governance mechanisms for managing analyses, intellectual property and patient privacy for studies that are conducted across decentralized databases
- Methods for stratifying patients across categories of risk, demographics and care treatments
- Approaches for the implementation of study and measures inclusion and exclusion criteria
- Means to create structured data from unstructured data such as the use of natural language processing to identify outcomes

PHSA 3011(a), as added by the Recovery Act, states that the Secretary shall invest in the infrastructure necessary to allow for and promote the electronic exchange and use of health information for each individual in the United States consistent with the goals outlined in the strategic plan developed by the National Coordinator. PHSA 3001(c)(3), as added by the Recovery Act, directs that the National Coordinator shall, "in consultation with other appropriate Federal agencies (including the National Institute of Standards and Technology), update the Federal Health IT Strategic Plan (developed as of June 3, 2008) to include specific objectives, milestones, and metrics with respect to" a specific set of topic areas. The current

Federal Health IT Strategic Plan (developed as of June 3, 2008), as referenced in the statute, advances "secondary use" as a key mode of information technology use to transform health care. This is consistent with, and will be updated and expanded upon pursuant to the direction of PHSA 3001(c)(3)(i), (vii) and (vii), as added by the Recovery Act, to add to the updated strategic plan such objectives, milestones, and metrics with respect to:

- *(Reference: PHSA 3001(c)(3)(i))* – the electronic exchange and use of health information and the enterprise integration of such information.
- *(Reference: PHSA 3001(c)(3)(vii))* – strategies to enhance the use of health IT in improving the quality of health care, reducing medical errors, reducing health disparities improving public health, increasing prevention and coordination with community resources, and improving the continuity of care among health care settings.
- *(Reference: PHSA 3001(c)(3)(viii))* – the specific plans for ensuring that populations with unique needs, such as children, are appropriately addressed in the technology design, as appropriate.

4b. SHARP Key Features

All Sites funded by the program will share the following key features:

- *Research Agenda*: Each Site will identify a unique set of project goals and strategies, commensurate with those of the over-arching program. Each Site will identify and implement an ambitious, research agenda addressing the specific goals of HITECH, the challenges to adoption and meaningful use that are critical to closing the gap between reality and the promise of health IT, as well as achieving the goal of a transformed health care delivery system.
- *Multidisciplinary Approach:* Each Site will work, as appropriate, to incorporate a multidisciplinary approach to addressing their specific area of focus. Disciplines relevant to this opportunity may include, but are not limited to: health informatics, clinical disciplines across the health professions, systems and industrial engineering, computer and information science, the biological sciences, behavioral science, mathematics and statistics, and health services research.
- *The Very Highest Level of Expertise and Coordination:* Addressing these breakthrough areas will require the most advanced thinking the nation can bring to bear. Arrangements that invoke the expertise of multiple institutions in support of each Site's activities are strongly encouraged. Targeted use of consultants to enhance the expertise available to a Site is also encouraged. Each Awardee will develop plans to utilize expertise, both internal and external, and help lead nationwide coordination efforts relevant to their research focus.
- *Relationship to ONC Programs:* Sites will work closely with other ONC programs making strategic contributions in health IT, including the Health IT Research Center, the Health IT Regional Extension Centers, grants to states to develop health information exchange, Health IT Beacon Communities, and other relevant programs as defined in Title XIII of the Recovery Act.
- *Near-term and Long-term Mission:* Each Site's research outcomes will include both near-term results developed to meet the specific needs of the healthcare community to achieve meaningful use and longer-term contributions to methods and fundamental knowledge. Applicants will be expected to work with industry, practitioners, and other partners to identify real-world health IT problems that both drive their Site's long-term research agenda and characterize the nature of their near-term results. For the first two years, roughly equal amounts of project effort should be devoted to short and long term

challenges.

- *Multi-Sector Partnerships:* Each Awardee will develop and sustain strong partnerships with the vendor community and other private sector health IT organizations as well as with practitioner organizations (e.g. hospitals, care providers, healthcare organizations and communities, and federal, state and local government entities) to enable productive exchange of information, speed knowledge and technology transfer, and support the Site. Partner organizations will contribute to the development and execution of the strategic and operational plans of the Site, embracing research outcomes and facilitating their transition into practice in both the near- and longer-term.
- *Institutional Commitment*: Each Awardee will demonstrate institutional commitment to the project, by making available the equipment, facilities, and laboratory space to the Site's activities; preference will be given to applications that maximize the fraction of awarded funds that are directly applied to research activities.
- *Project Evaluation*: Each Awardee will document, measure, and report its progress towards realizing its mission and goals using an evaluation plan that includes both formative and summative evaluation strategies. This report will be provided at specified intervals during the project, no less than annually.
- *Project Advisory Committee (PAC)*: Each Awardee will form a multi-stakeholder project advisory committee, including members of industry and representatives of professional organizations and institutions endeavoring to meaningfully use health IT, which will meet regularly to help align the work of the Site with external concerns and interests. Each Site's advisory committee will include in its membership ONC-identified federal liaisons that possess substantial subject-matter expertise relevant to the focus area of the Site. These members will be expected to report on progress and bring to ONC's immediate attention any potential problems. Non-ONC and non-federal membership of the PAC will be determined by the Site.

II. AWARD INFORMATION

1. Summary of Funding

Type of Applications Sought	New applications
Type of Award	Cooperative agreement
Approximate Amount of Funding Available in FY2010	$60,000,000
Average Award Amount	$15,000,000
Award Floor	$10,000,000
Award Ceiling	$18,000,000
Approximate Number of Awards	4
Project Period Length	4 years
Budget Period Length	4 years
Estimated Award Date	March 15, 2010
Anticipated Start Date	April 1, 2010

2. Funding Description

Awards will be in the form of a performance-based cooperative agreement with a four-year project period. Under this type of award, ONC will work collaboratively with each Awardee to accomplish the goals of the award.

Each cooperative agreement will anticipate a total budget of between $10 million and $18 million over the full four-year project period.

Consistent with HHS policy on cooperative agreements, the specific research agendas implemented by each Site will be determined in collaboration with ONC. Because funding is limited, priority will be given to those applicants that have: 1) identified an important, coherent, and parsimonious set of challenges within an identified focus area that are--or, if not addressed, will be--clear barriers to nationwide meaningful use of health IT and 2) describe a plan and demonstrate the capability to conduct both short and longer term research programs that will address these challenges.

Recipients will be required to track progress by collecting specific, uniform data about their research activities and progress toward milestones and outcomes (see Section II, Part 4, Evaluation and Milestones).

In accepting an ONC award, the recipient assumes legal, financial, administrative, and programmatic responsibility for administering the award in accordance with the terms and conditions of the award, as well as applicable laws, rules, regulations, and Executive Orders governing HHS assistance awards, all of which are incorporated into this award by reference. Failing to comply with these requirements may result in suspension or termination of the award and/or ONC's recovery of award funds.

3. Site Activities

Within its focus area, each Site will carry out at least the following set of activities:

- Initially define and subsequently update or redefine on a yearly basis, the key issues and research challenges within their respective area(s) of focus. The research areas identified will be those that significantly address barriers and solutions to achieving widespread adoption and meaningful use of health IT. Projects to address the identified issues will be

mapped to either a short-term (2 years) or long-term (4 years) timeframe. Because this is a cooperative agreement, recipients shall plan and allow for collaboration with ONC and other federal staff with relevant expertise – as identified or approved by ONC – in establishing and updating the definition of key issues and research challenges in the Site's focus area;

- Conduct ambitious research addressing these key issues and challenges. This work will draw on the scientific methods and expertise of researchers and practitioners in diverse fields;
- Collect specific, uniform data about the research activities and track progress toward milestones;
- Facilitate practical and efficient processes that enable translation of research into health care and public health innovations, facilitating the transition of multidisciplinary research outcomes into new healthcare products and services both the short- and long-term;
- Partner with industry to rapidly transfer short term results of this research into health IT products;
- Publish and otherwise disseminate these research findings, preferably in open source journals that maximize the accessibility of this knowledge to the entire health IT community;
- Participate in an external evaluation; and
- Select desired, measurable outcomes specific to the chosen research issue and methods for attaining results.

Note that the definition of IT products, as the focus of research translation and industry partnerships identified above, should be considered in the broadest possible sense and does not exclude those related to technologies developed in non-commercial settings or those intended to be distributed as part of an open-source technology platform. The results of research should be applicable and suitable for all platforms including open-source technology platforms. Applicants are strongly encouraged to propose development of technology using open-source approaches and release the outcomes of their research into open-source communities.

4. Evaluation and Milestones

Awardee progress toward performance-based key milestones and outcomes and will be regularly monitored on an ongoing basis. In the event an Awardee's progress is lagging, the ONC project officer for that award will work with the Awardee to furnish technical assistance aimed at improving the Awardee's performance.

Awardees will also be expected to participate in a more formal assessment of performance against key milestones, outcomes, and accomplishments expected by the 12th, 24th, and 36th th month of the award, pursuant to the applicant's project plan for activities under this grant. This assessment may be effected via a Site visit or through telecommunications technologies, .

The project plan of reference will be the applicant's proposed project plan, with any revisions made as a result of discussions with ONC, which is incorporated in the grant award.

ONC's evaluations will assess project performance and progress towards the key milestones specified below.

Potential questions for each domain of research might include but will not be limited to the following:

- To what extent do the research issues being pursued relate to challenges along pathway towards achieving meaningful use?
- How effective are the methods used to accelerate translation of research into health care?
- To what extent has the Site identified the salient, potentially breakthrough challenges?
- Are innovative research methods being applied to meet the ultimate research agenda?
- What problems have been encountered in implementing all of the required features of the Site?
- What relationships has the Site established with industry to facilitate the translation of the research?

The key project milestones include:

- In collaboration with the Site's Federal Steering Committee (FSC) (described in Section IV, Part 4b, below), developing an initial two year research work plan, delineating short term projects that will complete in two years, as well as longer term projects;
- Establishing a project advisory committee (PAC), to review research methods, results, and provide guidance;
- Establishing a network of multi-stakeholder relationships, including relationships with industry representatives;
- Establishing a plan to collaborate with other Sites and share research findings;
- Establishing plans to utilize expertise, both internal and external, in order to help lead nationwide coordination efforts relevant to their research focus;
- Implementing the plan to translate research outcomes into products and services in a timely manner;
- Establishing guidelines and/or proposals for accelerating the translation and integration of research outcomes into available products and services within the healthcare marketplace;
- Scheduling and conducting (as appropriate) and participating in expert panel meetings, FSC meetings, ONC team meetings and stakeholder meetings;
- Conducting and managing the short term research projects to conclusion in two years;
- Conducting and managing the long term projects to significant, demonstrable progress in two years; and
- Communicating research findings through appropriate mechanisms and making available as they are generated.

ONC will work with each Site to establish the specific performance evaluation criteria and milestones with guidance from the FSC.

III. ELIGIBILITY INFORMATION

1. Eligible Applicants

Any entity submitting an application for this award must be a U.S.-based:

- public or private institution of higher education; or
- other public or private institution or organization with a research mission.

2. Cost Sharing or Matching

Cost sharing or matching is not required for this award.

3. Application Screening and Responsiveness Criteria

Eligible institutions or organizations may apply for funds to establish Strategic Health IT Advanced Research Projects. An applicant may address, within a single application, one and only one of the four areas described above. An applicant may apply for support for establishment of more than one Site, but must do so by submitting a separate application for each Site for which it is applying for funding. An institution or organization submitting an application may also be a participating entity in an unlimited number of other applications for the same or other area(s).

3a. Application Screening Criteria

This section outlines administrative criteria that are required of all applicants. All applications will be screened to assure a level playing field for all applicants. Applications will not move forward unless these screening criteria are met.

a. The applicant meets eligibility requirements addressed in Section III, Part 1, Eligible Applicants.
b. The applicant submits a complete and timely application.
c. The project narrative does not exceed 40 double-spaced pages. This limit excludes biographical sketches, letters of support, program abstract, bibliography, and other attachments.
d. The application covers the elements listed below in its project narrative (see Section IV, Part 3c, Project Narrative).
e. Appendices are NOT used as a mechanism to exceed the page length restrictions of the project narrative.

3b. Application Responsiveness Criteria

This section outlines content criteria that are required for all applicants. Applications that do not meet the following responsiveness criteria will be administratively eliminated and will not receive further consideration.

a. The applicant has identified one and only one research focus area from the list provided in Section I, Part 4 above.
b. The application addresses both those challenges labeled as short term and those labeled as longer term.
c. The applicant has established collaborative relationships to transition results of short-term projects into products and best practices and has provided letters of commitment from those collaborators.
d. The applicant certifies that it has adopted nondiscrimination and conflict of interest policies that demonstrate a commitment to transparent, fair, nondiscriminatory, and unbiased practices.

IV. APPLICATION SUBMISSION INFORMATION

1. Letter of Intent

Applicants are requested, but not required, to submit a letter of intent to apply for this funding opportunity to assist ONC in planning for the program's independent review process. A letter of intent is not binding, and does not enter into the review of a subsequent application.

The letter of intent must be no longer than 2 pages, double-spaced, formatted to 8 ½" x 11" (letter-size) pages with 1" or larger margins on top, bottom, and both sides, and a font size of not less than 11 point.

The letter of intent must be received by January 4, 2010. Letters of intent must be sent electronically to the project officer Wil Yu, at Wil.Yu@HHS.gov.

Please refer to Appendix C for suggestions on the content of the letter. A letter of intent should specify the focus area that will be addressed by the application. If an institution expects to submit multiple applications, separate letters of intent for each submission should be written.

2. Address to Request and Submit Application Package

Application materials can be obtained from http://www.grants.gov. Inquiries should be sent to the project officer, Wil Yu, at Wil.Yu@HHS.gov.

Please note that ONC is requiring applications for all announcements to be submitted electronically through www.grants.gov. The Grants.gov registration process can take several days; **ONC strongly recommends that you do not wait until the application due date to begin the application process.** If your organization is not currently registered with www.grants.gov, please begin this process immediately. **For assistance with www.grants.gov, please contact them at** support@grants.gov **or 1-800-518-4726 24 hours a day, 7 days a week (excluding Federal holidays).**

At www.grants.gov, you will be able to download a copy of the application packet, complete it off-line, and then upload and submit the application via the Grants.gov website. Please note the following instructions:

- You may access the electronic application for this program on www.Grants.gov. You may search for the downloadable application page by the Funding Opportunity Number HHS-2010-ONC-TR-005 or CFDA number 93.728.
- Online instructions are embedded in the SF-424 R&R form fields—simply scroll your mouse over the field. Applicants may also take advantage of the online tutorials, FAQs, and resources available online at www.Grants.gov.
- **You must submit all documents electronically via Grants.gov,** including all information included on the SF-424 (R&R) and all necessary assurances and certifications.
- All applicants must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number. There is no fee to complete this process. **Note: a missing or incorrect DUNS number is the primary reason for an application to be "Rejected for Errors by Grants.gov.**
- All applicants must register in the Central Contractor Registry (CCR). There is no fee to complete this process. Applicants should allow a minimum of five days to complete the CCR registration if they have not registered in the past. If an applicant has already registered with CCR but has not renewed their registration in the last 12 months, they will need to renew their registration at www.ccr.gov. The renewal can be done online and will take about 30 minutes.
- Prior to application submission, Microsoft Vista and Office 2007 users should review the Grants.gov compatibility information and submission instructions provided at www.grants.gov (click on "Vista and Microsoft Office 2007 Compatibility Information").
- Your application must comply with any page limitation requirements described in this Program Announcement.
- After you electronically submit your application, you will receive an automatic acknowledgement from www.grants.gov that contains a Grants.gov tracking number. ONC will retrieve your application form from Grants.gov.

- After ONC retrieves your application form from Grants.gov, a return receipt will be emailed to the applicant contact. This will be in addition to the validation number provided by Grants.gov.
- According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-XXXX. The time required to complete this information collection is estimated to average 150 hours per response, including the time to review instructions, search existing data resources, gather the data needed and complete and review the information collection.
- If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Avenue, SW, Suite 537-H, Washington, DC 20201 Attention: PRA Reports Clearance Officer.

APPLICATIONS CANNOT BE ACCEPTED THROUGH ANY EMAIL ADDRESS OR THROUGH ANY WEBSITE OTHER THAN www.grants.gov. APPLICATIONS CANNOT BE RECEIVED VIA PAPER MAIL, FAX, COURIER, OR DELIVERY SERVICE.

APPLICANTS ARE STRONGLY ENCOURAGED TO COMPLETE AND SUBMIT APPLICATIONS AS FAR IN ADVANCE OF THE SUBMISSION DEADLINE AS POSSIBLE. THE APPLICATION, INCLUDING ALL REQUIRED ATTACHMENTS AND INCLUDED FILES FOR POTENTIAL CONSIDERATION IN THE REVIEW PROCESS, MUST BE RECEIVED BY 11:59 PM EASTERN TIME ON THE DATE SPECIFIED IN SECTION IV, PART 4, APPLICATION SUBMISSION DATES AND TIMES, BELOW.

3. Content and Form of Application Submission

The application must include the following components.

3a. DUNS Number

- The Office of Management and Budget requires applicants to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for federal grants or cooperative agreements on or after October 1, 2003. It is entered on the SF-424 (R&R). (For more information on the forms required within the application package, see Appendix D). It is a unique, nine-digit identification number, which provides unique identifiers of single business entities. The DUNS number is *free and easy* to obtain. **Note: a missing or incorrect DUNS number is the primary reason for an application to be "Rejected for Errors by Grants.gov.**

Organizations can receive a DUNS number at no cost by calling the dedicated toll-free DUNS Number request line at 1-866-705-5711 or by using this link to access a guide: https://www.whitehouse.gov/omb/grants/duns_num_guide.pdf **.**

3b. Project Abstract

Applicants shall include a one-page abstract (no more than 1000 words) in the application. This abstract is often distributed to provide information to the public and Congress and represents a high-level summary of the project. As a result, applicants should prepare a clear, accurate, concise abstract that can be understood without reference to other parts of the application and that

provides a description of the proposed project, including: the project's goal(s), objectives, overall approach, anticipated outcomes, products, and duration. The project abstract must be double-spaced, formatted to 8 ½" x 11" (letter-size) pages with 1" or larger margins on top, bottom, and both sides, and a font size of not less than 11 point.

The applicant shall place the following information at the top of the narrative abstract (this information is not included in the 1000 word maximum):

- Research Focus Area
- Applicant Name: Institution and Primary Investigator
- Address
- Contact Name
- Contact Phone Numbers (Voice, Fax)
- E-Mail Address
- Web Site Address, if applicable

3c. Project Narrative

The project narrative must be double-spaced, formatted to 8 ½" x 11" (letter-size) pages with 1" or larger margins on top, bottom, and both sides, and a font size of not less than 11 point. Project narratives may address either one or two proposed research areas.

Forty pages is the maximum length allowed for an application proposing to address one research area. These limits exclude biographical sketches, letters of support, program abstract, organizational chart, and literature cited. ONC will not accept applications with a project narrative that exceeds the limits specified above.

The project narrative is the part of the application that will offer the most substantive information about the proposed project, and it will be used as the primary basis to determine whether or not the project meets the minimum requirements for awards under the Recovery Act. The project narrative should provide a clear and concise description of your project.

(Note: a concise resource offering tips for writing proposals for HHS grants can be accessed via the Web at: http://www.hhs.gov/grantsnet/AppTips.htm)

Your project narrative should include the following components. These components will be counted as part of the page limit. The suggested lengths of the sections, given below, are guidelines to help applicants create a balanced document, and not mandatory restrictions.

- Research Topic, Vision Statement, and Key Challenges (3-5 pages)
- Proposed Approach (13-18 pages)
- Plan for Transitioning Appropriate Research Results into Practice (3-4 pages)
- Committees and Stakeholder Involvement (2-3 pages)
- Project Management (2-4 pages)
- Evaluation (1-2 pages)
- Organizational Capability (3-5 pages, exclusive of biosketches and organizational chart)

Research Topic, Vision Statement, and Key Challenges. This section should offer the applicant's conceptualization of the selected research focus area. This should also include, from the applicant's perspective, a specific delineation of the research challenges the proposed Site will

address, specifically distinguishing between challenges that can be addressed in the short term (2 years) and those which will require four years. (3-5 pages).

Proposed Approach. This section should provide a clear and concise description of the approach the applicant is proposing to use to conduct the research including identifying the major challenges in the focus area. This section should be organized so that the relationship of each element of the plan to each of the research challenges is completely clear. Additionally, the research plan should include proposed strategies on how the results of the project may be disseminated.

Each element of the research plan should be described as a discrete project, and each project should have an separately itemized budget as described below. Each project must be clearly identified as having short-term (2 year) and/or long-term (4 year) objectives delineated for each component. While the applicant institution and sub-awardees may undertake projects that exclusively involve personnel at their own institutions, the integration and cohesiveness of the Site will be enhanced by projects on which personnel from multiple Sites directly collaborate.

The research plan should include as much detail as possible given the page limitation. Notwithstanding, the plan for each project, at a minimum, **must state**, (a) specific aims, (b) previous work of the investigative team on which the proposed research is **directly** based, (c) the methods that will be applied, the anticipated outcomes of the work and their potential significance in addressing the challenges to the adoption of health IT; and (d) the key personnel who will be involved.

Statements of previous work should not be redundant with general statements of experience in the "organizational capability" section described below. All key personnel mentioned in this section must have biosketches provided in a separate section of the application. (13-18 pages)

Plan for Transitioning Appropriate Research Results into Practice. This section should describe a plan for engaging health IT stakeholders and interested groups in promoting the transition of appropriate research results into health IT products, tools, and best practices. The plan should be specific in proposing activities that will transition the results of the proposed short term (2 year) projects in products and best practices. Collaborative arrangements with industry and other groups outside the applicant institution should be accompanied by appropriate letters of support. (3-4 pages)

Committees and Stakeholder Involvement. This section should describe plans to establish and operate the proposed Site's project advisory committee (PAC), including names of at least 10 members who have committed to join. Commitment letters from these named individuals must be included (see 3f below) as part of the application. Additional activities to promote stakeholder involvement, including efforts to help lead coordination efforts around the relevant research area of focus, should be described. (2-3 pages)

Project Management. This section should include a clear delineation of the roles and responsibilities of the principal investigator, participating researchers, project staff, consultants and collaborating organizations, and how they will contribute to achieving the research objectives and outcomes. If the application includes sub-awards with contractual relationships, plans for coordinating research activities across multiple organizations and Sites should be described. This section should specify who would have day-to-day responsibility for key tasks such as: leadership of project; monitoring the project's on-going progress, preparation of reports; communications

with other collaborating organizations, the Site's Federal Steering Committee (FSC), and ONC. (2-4 pages)

Evaluation. Recipients will be required to maintain information relevant to achieving the milestones and performance-based outcomes specified in Section II, Part 4, Evaluation and Milestones. The application should describe the approach that will be used to assess project performance and monitor and track progress toward meeting key milestones. (1-2 pages)

Organizational Capability Statement. For all facets the focus research area the application should include an organizational capability statement and curriculum vitae for key project personnel, including all researchers and other key personnel who will participate in the Site's work.

The statement should outline the established research program relevant to the research focus area and highlight established collaborative relationships with healthcare stakeholders including, but not limited to, other academic and research institutions, healthcare providers, payors, consumers & end-users, local / state governments, and health IT vendors and innovators within the healthcare industry. Note that the definition of IT products, vendors and organizations should be considered in the broadest possible sense and does not exclude those related to technologies developed in non-commercial settings or those meant to be distributed as part of an open-source technology platform. Applicants are strongly encouraged to propose development of technology using open-source approaches and release the outcomes of their research into open-source communities.

The statement should highlight potential strategies the organization may employ in an effort to sustain research efforts beyond the scope of the project timeframe.

Include the relevant organizational resources available to perform the proposed project (e.g., facilities, equipment, and other resources). The statement should also highlight capabilities of the applicant not included in the program narrative, such as any current or previous relevant experience and/or the record of the project team in preparing cogent and useful reports, publications, research studies and other products. Examples of these may be included in the appendix material.

Neither vitae nor an organizational chart will count towards the narrative page limit. Also include information about any organization(s) that will have a significant role(s) in the research project and achieving research goals, including those proposed to receive sub-awards. (3-5 pages)

3d. Literature Cited

Applications should justify their arguments through reliance on relevant scholarly articles and other literature. Up to 100 citations may be included. Citations will be judged by quality, not quantity. Applicants should avoid multiple, partially-redundant citations. Where an assertion in the narrative is supported by a large number of citations, the narrative might state the number of citations that support the assertion and then include in the citation list only the most important exemplars.

3e. Work Plan

The Work Plan must be formatted to 8 ½" x 11" (letter-size) pages with 1" or larger margins on top, bottom, and both sides, and a font size of not less than 11 point. The Project Work Plan

should reflect and be consistent with the project narrative and budget and should cover the budget years (total of up to four years) of the project period. For each major task or action step, the work plan should identify timeframes involved, including start- and end-dates.

3f. Letters of Commitment from Key Participating Organizations and Agencies

Include confirmation of the commitments to the project (should it be funded) made by key collaborating organizations and agencies in this part of the application. Any organization that is specifically named to have a significant role in carrying out the project should be considered an essential collaborator. Signed letters of commitment should be scanned and included as attachments. In your transmission, be sure to include the funding opportunity number and your organization's name.

3g. Budget Narrative / Justification

The Budget Narrative / Justification must be formatted to 8 ½" x 11" (letter-size) pages with 1" or larger margins on top, bottom, and both sides, and a font size of not less than 11 point. Each application should include a detailed budget for each year of the project period with and a detailed summary of the request for all four years.

The applicant may request up to $18 M total costs for up to 4 years, inclusive of indirect costs. A typical budget could include (but is not restricted to) these elements:

- Salary support for faculty members and staff involved, organized by components named in the project narrative (Section IV, Part 3c above)
- Costs for research methods development
- Costs for development/purchase of tools and techniques
- Costs for other required support
- Facilities and administration costs at a federally approved indirect cost rate

A combined multi-year Budget Narrative/ Justification, as well as a detailed Budget Narrative/Justification for each year of potential funding is required. The detailed summary request must be itemized separately for each research project, as identified within the Project Narrative. Detailed budget narratives / justifications must also be provided for each contractor for each year of potential funding. Costs for management of the Site as a whole should be itemized in a separate section of the budget. Priority will be given to applications that minimize administrative costs while still provided coherent management of an integrated Site.

If the application includes one or more sub-awards to go to organizations external to the applicant institution, fully executed budgets from each prospective sub-awardee must be included, along with a letter of commitment signed by an authorized institutional officer.

Except for the procurement of such items as commercially available supplies, materials, equipment or general support services allowable under the award, no significant part of the research or substantive effort may be contracted or otherwise transferred to another organization without prior ONC authorization. The intent to enter into such arrangements must be disclosed in the application, and a separate budget should be provided for each sub-awardee, if already identified, along with a description of the work to be performed. Otherwise, the disclosure should include a clear description of the work to be performed, and the basis for selection of the sub-awardee (except for collaborative/joint arrangements).

Applicants and or grantees are responsible for ensuring that their organization and or institution has in place an established and adequate procurement system with fully developed written procedures for awarding and monitoring all contracts. Applicants must provide a clear explanation as to the purpose of each contract, how the costs were estimated, and the specific contract deliverables.

3h. Appendices

Applicants may submit no more than 30 pages of appendix material. Appendix material should be used to provide additional materials (for example, key papers or reports or excerpts) that will be of assistance in evaluating the merit of the application. Applications that use appendix material as a mechanism to exceed the page length limitations of the project narrative will not be considered for award.

4. Application Submission Dates and Times

The deadline for submission of the optional Letter of Intent is 11:59 p.m., Eastern Time, on January 4, 2010. The deadline date for submission of applications is 11:59 p.m., Eastern Time, on January 25, 2010.

Applications that fail to meet the application due date will **not** be reviewed or evaluated for award.

Grants.gov will automatically send applicants a tracking number and date of receipt verification electronically once the application has been successfully received and validated in Grants.gov. After ONC retrieves your application form from Grants.gov, a return receipt will be emailed to the applicant contact. This will be in addition to the validation number provided by Grants.gov.

5. Intergovernmental Review

This funding opportunity announcement is not subject to the requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs."

6. Funding Restrictions

Funds under this announcement cannot be used for the following purposes:

- To supplant or replace current public or private funding.
- To supplant on-going or usual activities of any organization involved in the project.
- To purchase or improve land, or to purchase, construct, or make permanent improvements to any building except for minor remodeling.
- To reimburse pre-award costs.
- To conduct basic research (e.g. scientific or medical experiments)

Funds are to be used in a manner consistent with program policies developed by ONC. Allowable administrative functions/costs include:

- Usual and recognized overhead, including indirect rates for all consortium organizations that have a federally approved indirect cost rate; and
- Management and oversight of specific project components funded under this program.

The Recovery Act also requires that the recipient comply with additional funding limitations described in Section VI, Part 5 of this funding announcement.

V. APPLICATION REVIEW INFORMATION

1. Application Review Criteria

Applications are scored by assigning a maximum of 100 points across four criteria:

- Understanding of Project Purpose - (10 points)
- Approach, Work Plan and Activities - (40 points)
- Applicant Capabilities - (30 points)
- Budget, Level of Effort, and Justification - (20 points)

1a. Understanding of Project Purpose (10 points)

- The extent to which the applicant has identified an important, coherent, and parsimonious set of challenges and associated research questions within an identified focus area that are—or, if not addressed, will be—clear barriers to nationwide meaningful use of health IT.

1b. Approach, Work Plan and Activities (40 points)

- The extent to which the proposed research addresses the identified challenges (5 points)
- The extent to which the proposed research methods promise to address the challenges with breakthrough findings on the proposed timeline (15 points)
- The balance and appropriateness of the characterization of projects as short term and longer-term, and the balance between them. (5 points)
- The extent to which the plan to transition results of short term projects to products and best practices is complete and feasible; and envisions the release of the outcomes of their research into open-source communities. (15 points)

1c. Applicant Capabilities (30 points)

- Strength of evidence that the project brings the very highest level of research talent for the chosen focus area and strength of evidence that the project will integrate the efforts of these researchers. (20 points).
- Extent to which the proposed activities bring to bear all the resources necessary to perform the proposed work and the identification of proposed strategies to sustain research efforts beyond the project time-frame (10 points)

1d. Budget, Level of Effort, and Justification (20 points)

- Extent to which the proposed levels of effort of the project director(s), key personnel and consultants are adequate to advance the project in accordance with the timelines (10 points)
- Extent to which the budget is justified with respect to the adequacy and reasonableness of resources requested, and the amount of the budget allocated to administration is minimized while still allowing coherent management of an integrated Site. (10 points)

2. Review and Selection Process

Applications that are complete and responsive to the funding announcement criteria will be evaluated for scientific and technical merit. HHS ONC will convene an objective review panel in accordance with HHS objective review procedures using the review criteria stated above. Applications that are incomplete or non-responsive to the funding announcement criteria will not be considered for award.

As part of the objective review, all invited applications will:

- be independently reviewed and scored by an objective review panel member;
- be discussed and scored by the panel; and
- be provided with a written critique.

The following will be considered in making funding decisions:

- merit of the proposed project as determined by objective review;
- availability of funds; and
- relevance of the proposed project to program priorities.

VI. AWARD ADMINISTRATION INFORMATION

1. Award Notices

Successful applicants will receive an electronic Notice of Award in March 2010. The Notice of Award is the authorizing document from the ONC authorizing official. Unsuccessful applicants are notified within 30 days of the final funding decision and will receive a disapproval letter via e-mail or U.S. mail.

2. Administrative and National Policy Requirements

The award is subject to DHHS Administrative Requirements, which can be found in 45CFR Part 74 and the Standard Terms and Conditions implemented through the HHS Grants Policy Statement located at ftp://ftp.hrsa.gov/grants/hhsgrantspolicystatement.pdf.

3. Post-Award Reporting Requirements

All reporting requirements will be provided to applicants of successful full applications, adherence to which is a required condition of any award. In general, the successful applicant under this guidance must comply with the following reporting and review activities:

3a. Audit Requirements

The recipient shall comply with audit requirements of Office of Management and Budget (OMB) Circular A-133. Information on the scope, frequency, and other aspects of the audits can be found on the Internet at www.whitehouse.gov/omb/circulars;

3b. Financial Status Reports

Until such time as HHS migrates to the SF-425 FFR, the recipient shall submit one final Financial Status Report (FSR) using form SF-269 annually and at the end of the four year budget period. An FSR is due no later than 90 days annually and after the budget period. Failure to submit this report in a timely manner could affect future funding. The report is the accounting of expenditures under the project. More specific information on this reporting requirement will be included in the Notice of Award.

3c. Performance Reports

The Awardee shall submit annual progress reports related to their projects and overall Site performance. A specific Performance Report format will be finalized between the Awardee and ONC following the award date.

In accepting an ONC award, the recipient assumes legal, financial, administrative, and programmatic responsibility for administering the award in accordance with the terms and conditions of the award, as well as applicable laws, rules, regulations, and Executive Orders governing HHS assistance awards, all of which are incorporated into this award by reference. Failing to comply with these requirements may result in suspension or termination of the award and/or ONC's recovery of award funds.

3d. Recovery Act-Specific Reporting

Quarterly Financial and Programmatic Reporting: Consistent with the Recovery Act's emphasis on accountability and transparency, reporting requirements under Recovery Act programs will differ from and expand upon HHS's standard reporting requirements for grants and cooperative agreements. In particular, Section 1512(c) of the Recovery Act sets out detailed requirements for quarterly reports that must be submitted within 10 days of the end of each calendar quarter. The information from recipient reports will be posted on a public website. To the extent that funds are available to pay a recipient's administrative expenses, those funds may be used to assist the recipient in meeting the accelerated time-frame and extensive reporting requirements of the Recovery Act.

Additional instructions and guidance regarding required reporting will be provided as they become available. For planning purposes, however, all applicants shall be aware that Recovery Act Section 1512(c) provides as follows regarding recipient reports:

Not later than 10 days after the end of each calendar quarter, each recipient that received recovery funds from a federal agency shall submit a report to that agency that contains—

(1) the total amount of recovery funds received from that agency;
(2) the amount of recovery funds received that were expended or obligated to projects or activities; and
(3) a detailed list of all projects or activities for which recovery funds were expended or obligated, including--
    (A) the name of the project or activity;
    (B) a description of the project or activity;
    (C) an evaluation of the completion status of the project or activity;
    (D) an estimate of the number of jobs created and the number of jobs retained by the project or activity; and
    (E) for infrastructure investments made by state and local governments, the purpose, total cost, and rationale of the agency for funding the infrastructure investment with funds made under this Act, and name of the person to contact at the agency if there are concerns with the infrastructure investment.
(4) Detailed information on any sub-contracts or sub-grants awarded by the recipient to include the data elements required to comply with the federal Funding accountability and Transparency Act of 2006 (Public Law 109-282), allowing aggregate reporting on awards

below $25,000 or to individuals, as prescribed by the Director of the Office of Management and Budget.

OMB guidance for implementing and reporting Recovery Act activities can be found at http://www.whitehouse.gov/omb/recovery_default/

Information related to reporting the number of jobs created and the number of jobs retained as required by the Recovery Act is contained in Appendix F.

4. Cooperative Agreement Terms and Conditions of Award

4a. Recipient Responsibilities

A cooperative agreement is an award instrument of financial assistance where substantial involvement is anticipated between ONC and the recipient during the performance of the project. Recipients retain the primary responsibility and dominant role for planning, directing and executing the proposed project as outlined in the terms and conditions of the cooperative agreement. Recipient responsibilities include:

- Requirements – Recipients shall comply with all Site Activities outlined in Section II, Part 3.
- Collaboration – Recipients are required to collaborate with , on a regular specified basis, the critical stakeholders listed in this Funding Opportunity Announcement, ONC staff including but not limited to the Site's assigned Project Officer, and other federal staff identified by ONC, including the Site Federal Steering Committee (FSC) (described in Section IV, Part 4b, below). ONC staff will report if recipients' progress is lacking or lagging.
- Reporting – Recipients are required to comply with all reporting requirements outlined in this Funding Opportunity Announcement and the terms and conditions of the cooperative agreement.

4b. ONC Responsibilities

ONC will be involved with the recipient's process of designing the research agenda by working collaboratively with the recipient to set broad priorities and identify strategies to accomplish the objectives of this announcement. ONC, and/or its representatives, will provide the following types of support to the Strategic Health IT Advanced Research Projects:

- Consultation and technical assistance in planning, operating, and evaluating the design activities;
- Information about ONC programs relevant to the design activities;
- Facilitate coordination/collaboration with other Federal agencies and ONC HITECH programs and award recipients.
- Review of activities on a regular, specified basis and feedback to ensure that objectives and award conditions are being met.
- Review and approve members of each SHARP's advisory committees
- Guide, facilitate, and/or assist with the dissemination of SHARP results and/or findings.

ONC will establish and coordinate a Federal Steering Committee (FSC) composed of government employees to support its oversight of this program. The FSC will, through ONC and the each SHARP site's project officer, work with the SHARP sites to shape the research agendas, and collaborate with ONC in the establishment and execution of the program. In addition to ONC personnel, the FSC will include representatives from such agencies as the

Office of the Secretary (CTO), National Institute of Standards and Technology (Director of Health Informatics), the National Science Foundation (Assistant Director/Program Director), the Agency for Healthcare Research and Quality (CIO/Health IT Director), the National Institutes of Health (Program Director), the Food and Drug Administration, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, the Department of Veterans' Affairs, Office of Science & Technology Policy (CTO), and the Department of Defense. Members of the FSC may also be identified as representatives of ONC for purposes of consulting and collaborating with the SHARP sites, and serve as members of the SHARP site's Advisory Committees (as described in Section I, Part 4b). The FSC will meet regularly with recipients to ensure that objectives and award conditions are met.

4c. Joint Responsibilities

Under the cooperative agreement, ONC requires that certain activities be planned jointly and include approval from ONC. Therefore, the specific research agenda for each SHARP will be finalized / established through a collaborative process between applicants and ONC. Cooperative agreements will include terms and conditions reserving the ability of ONC to negotiate further modifications to research agenda during the course of the awarded project period that are in the best interest of the program. . To further this collaboration, the Awardees and ONC will meet regularly as a group to share progress reports and to make decisions about the research methods, tools format of study and study results, timelines, training approaches, and other topics as needed.

4d. Modifications and Amendments

Once a cooperative agreement is in place, requests to modify or amend the agreement or the work plan may be made by ONC or the recipient pursuant to HHS grant policy and regulations.

4e. Intellectual Property

The Government reserves all rights granted by and the recipient agrees to be bound by HHS regulations regarding rights in intangible property, 45 C.F.R. § 74.3, which is specifically incorporated herein. Generally, the recipient may copyright any work that is subject to copyright and was developed, or for which ownership was purchased, under this award. The Government reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

4f. Dispute Resolution

Both ONC and the recipient are expected to work in a collegial fashion to minimize misunderstandings and disagreements. Pursuant to 45 C.F.R. §74.3, ONC will resolve disputes by using alternative dispute resolution (ADR). ADR often is effective in reducing the cost, delay, and contentiousness involved in appeals and other traditional ways of handling disputes. ONC will determine the specific technique to be employed on a case-by-case basis. ADR techniques include mediation, neutral evaluation, and other consensual methods. The National Coordinator for Health IT will make final determinations pertaining to cooperative agreements based on the output of these resolution methods and in accordance with 45 C.F.R. Part 74.

5. Recovery Act Terms and Conditions

The following are the standard terms and conditions for Recovery Act grant programs.

5a. HHS Standard Terms and Conditions

HHS award recipients must comply with all terms and conditions outlined in their award, including policy terms and conditions contained in applicable (HHS) Grant Policy Statements, and requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable, unless they conflict or are superseded by the terms and conditions implementing the Recovery Act's requirements below.

In addition to the standard terms and conditions of award, recipients receiving funds under Division A of the Recovery Act must abide by the terms and conditions set out below. The terms and conditions below concerning civil rights obligations and disclosure of fraud and misconduct are reminders rather than new requirements, but the other requirements are new and are specifically imposed for awards funded under the Recovery Act. Recipients are responsible for contacting their HHS grant/program managers for any needed clarifications.

5b. Preference for Quick Start Activities

In using funds for this award for infrastructure investment, recipients shall give preference to activities that can be started and completed expeditiously, including a goal of using at least 50 percent of the funds for activities that can be initiated not later than 120 days after the date of the enactment of the Recovery Act. Recipients shall also use funds in a manner that maximizes job creation and economic benefit. (Recovery Act Sec. 1602)

5c. Limit on Funds

None of the funds appropriated or otherwise made available in the Recovery Act may be used by any state or local government, or any private entity, for any casino or other gambling establishment, aquarium, zoo, golf course, or swimming pool. (Recovery Act Sec. 1604)

5d. Recovery Act: One-Time Funding

Unless otherwise specified, Recovery Act funding to existent or new recipients should be considered one-time funding.

5e. Civil Rights Obligations

While the Recovery Act has not modified Awardees' civil rights obligations, which are referenced in the HHS Grants Policy Statement, these obligations remain a requirement of federal law. Recipients and sub-recipients of Recovery Act funds or other federal financial assistance must comply with Title VI of the Civil Rights Act of 1964 (prohibiting race, color, and national origin discrimination), Section 504 of the Rehabilitation Act of 1973 (prohibiting disability discrimination), Title IX of the Education Amendments of 1972 (prohibiting sex discrimination in education and training programs), and the Age Discrimination Act of 1975 (prohibiting age discrimination in the provision of services). For further information and technical assistance, please contact the HHS Office for Civil Rights at (202) 619-0403, OCRmail@hhs.gov, or http://www.hhs.gov/ocr/civilrights/.

5f. Disclosure of Fraud or Misconduct

Each recipient or sub-recipient awarded funds made available under the Recovery Act shall promptly refer to the HHS Office of Inspector General any credible evidence that a principal, employee, agent, contractor, sub-recipient, sub-contractor, or other person has submitted a false claim under the False Claims Act or has committed a criminal or civil violation of laws pertaining to fraud, conflict of interest, bribery, gratuity, or similar misconduct involving those funds. The HHS Office of Inspector General can be reached at http://www.oig.hhs.gov/fraud/hotline/.

5g. Recovery Act Transactions Listed in Schedule of Expenditures of Federal Awards and Recipient Responsibilities for Informing Sub-Recipients

(a) To maximize the transparency and accountability of funds authorized under the Recovery Act as required by Congress and in accordance with 45 CFR 74.21 "Uniform Administrative Requirements for Grants and Agreements", as applicable, and OMB A-102 Common Rules provisions, recipients agree to maintain records that identify adequately the source and application of Recovery Act funds.

(b) For recipients covered by the Single Audit Act Amendments of 1996 and OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations," recipients agree to separately identify the expenditures for federal awards under the Recovery Act on the Schedule of Expenditures of Federal Awards (SEFA) and the Data Collection Form (SF-SAC) required by OMB Circular A-133. This shall be accomplished by identifying expenditures for federal awards made under the Recovery Act separately on the SEFA, and as separate rows under Item 9 of Part III on the SF-SAC by CFDA number, and inclusion of the prefix "ARRA-" in identifying the name of the federal program on the SEFA and as the first characters in Item 9d of Part III on the SF-SAC.

(c) Recipients agree to separately identify to each sub-recipient, and document at the time of sub-award and at the time of disbursement of funds, the federal award number, CFDA number, and amount of Recovery Act funds. When a recipient awards Recovery Act funds for an existing program, the information furnished to sub-recipients shall distinguish the sub-awards of incremental Recovery Act funds from regular sub-awards under the existing program.

(d) Recipients agree to require their sub-recipients to include on their SEFA information to specifically identify Recovery Act funding similar to the requirements for the recipient SEFA described above. This information is needed to allow the recipient to properly monitor sub-recipient expenditure of Recovery Act funds as well as oversight by the federal awarding agencies, Offices of Inspector General and the Government Accountability Office.

5h. Recipient Reporting

Reporting and Registration Requirements under Section 1512 of the Recovery Act:

(a) This award requires the recipient to complete projects or activities which are funded under the Recovery Act and to report on use of Recovery Act funds provided through this award. Information from these reports will be made available to the public.

(b) The reports are due no later than ten calendar days after each calendar quarter in which the recipient receives the assistance award funded in whole or in part by the Recovery Act.

(c) Recipients and their first-tier recipients must maintain current registrations in the Central Contractor Registration (www.ccr.gov) at all times during which they have active federal awards funded with Recovery Act funds. A Dun and Bradstreet Data Universal Numbering System (DUNS) Number (www.dnb.com) is one of the requirements for registration in the Central Contractor Registration.

(d) The recipient shall report the information described in Section 1512(c) using the reporting instructions and data elements that will be provided online at www.FederalReporting.gov and ensure that any information that is pre-filled is corrected or updated as needed.

5i. Wage Rate Requirements under Section 1606 of the American Recovery and Reinvestment Act of 2009

Section 1606 of the Recovery Act requires that all laborers and mechanics employed by

contractors and subcontractors on projects funded directly by or assisted in whole or in part by and through the Federal Government pursuant to the Recovery Act shall be paid wages at rates not less than those prevailing on projects of a character similar in the locality as determined by the Secretary of Labor in accordance with subchapter IV of chapter 31 of title 40, United States Code.

Pursuant to Reorganization Plan No. 14 and the Copeland Act, 40 U.S.C. 3145, the Department of Labor has issued regulations at 29 CFR Parts 1, 3, and 5 to implement the Davis-Bacon and related Acts. Regulations in 29 CFR 5.5 instruct agencies concerning application of the standard Davis-Bacon contract clauses set forth in that section. Federal agencies providing grants, cooperative agreements, and loans under the Recovery Act shall ensure that the standard Davis-Bacon contract clauses found in 29 CFR 5.5(a) are incorporated in any resultant covered contracts that are in excess of $2,000 for construction, alteration or repair (including painting and decorating).

(b) For additional guidance on the wage rate requirements of section 1606, contact your awarding agency. Recipients of grants, cooperative agreements and loans should direct their initial inquiries concerning the application of Davis-Bacon requirements to a particular federally assisted project to the Federal agency funding the project. The Secretary of Labor retains final coverage authority under Reorganization Plan Number 14.

VII. AGENCY CONTACTS

Wil Yu
Project Officer
U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Telephone: 202-690-5920
Email: Wil.Yu@HHS.gov

Shonda Gosnell
Grants Management Specialist
HRSA Division of Grants Management Operations
Telephone: 301-443-4238
E-Mail: sgosnell@hrsa.gov

VIII. OTHER INFORMATION

This funding announcement is subject to restrictions on oral conversations during the period of time commencing with the submission of a formal application by an individual or entity and ending with the award of the competitive funds. Federal officials may not participate in oral communications initiated by any person or entity concerning a pending application for a Recovery Act competitive grant or other competitive form of federal financial assistance, whether or not the initiating party is a federally registered lobbyist. This restriction applies unless:

- the communication is purely logistical;
- the communication is made at a widely attended gathering;
- the communication is to or from a federal agency official and another federal Government employee;
- the communication is to or from a federal agency official and an elected chief executive of a state, local or tribal government, or to or from a federal agency official and the Presiding Officer or Majority Leader in each chamber of a state legislature; or
- the communication is initiated by the federal agency official.

For additional information, see:
http://www.whitehouse.gov/omb/assets/memoranda_fy2009/m09-24.pdf

Additional information not previously mentioned within this Funding Opportunity Announcement is included in the Appendices in the following topic areas:

- Conflict of Interest Certification (Appendix E)
- Recovery Act-Required Performance Measures (Appendix F)

IX. Appendices

A. Statutory Text for Health Information Strategic Health IT Advanced Research Projects
B. Additional Information on SHARP Research Focus Areas
C. Suggested Content for Letter of Intent to Apply
D. Required Documents for SHARP Applications
E. Conflict of Interest Certification Template
F. Recovery Act-Required Performance Measures

Appendix A – Statutory Text for Strategic Health IT Advanced Research Projects

The Strategic Health IT Advanced Research Projects program is authorized by Section 3011 of the PHSA, as added by the Recovery Act. The full text of PHSA 3017 follows.

SEC. 3011. IMMEDIATE FUNDING TO STRENGTHEN THE HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.
‘‘(a) IN GENERAL.—The Secretary shall, using amounts appropriated under section 3018, invest in the infrastructure necessary to allow for and promote the electronic exchange and use of health information for each individual in the United States consistent with the goals outlined in the strategic plan developed by the National Coordinator (and as available) under section 3001.

The Secretary shall invest funds through the different agencies with expertise in such goals, such as the Office of the National Coordinator for Health Information Technology, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, the Centers of Medicare & Medicaid Services, the Centers for Disease Control and Prevention, and the Indian Health Service to support the following:

‘‘(1) Health information technology architecture that will support the nationwide electronic exchange and use of health information in a secure, private, and accurate manner, including connecting health information exchanges, and which may include updating and implementing the infrastructure necessary within different agencies of the Department of Health and Human Services to support the electronic use and exchange of health information.

‘‘(2) Development and adoption of appropriate certified electronic health records for categories of health care providers not eligible for support under title XVIII or XIX of the Social Security Act for the adoption of such records.

‘‘(3) Training on and dissemination of information on best practices to integrate health information technology, including electronic health records, into a provider’s delivery of care, consistent with best practices learned from the Strategic Health IT Advanced Research Projects developed under section 3012(b), including community health centers receiving assistance under section 330, covered entities under section 340B, and providers participating in one or more of the programs under titles XVIII, XIX, and XXI of the Social Security Act (relating to Medicare, Medicaid, and the State Children’s Health Insurance Program).

‘‘(4) Infrastructure and tools for the promotion of telemedicine, including coordination among Federal agencies in the promotion of telemedicine.

‘‘(5) Promotion of the interoperability of clinical data repositories or registries.

‘‘(6) Promotion of technologies and best practices that enhance the protection of health information by all holders of individually identifiable health information.

‘‘(7) Improvement and expansion of the use of health information technology by public health departments.

SEC. 3017. GENERAL GRANT AND LOAN PROVISIONS.

(a) Reports- The Secretary may require that an entity receiving assistance under this subtitle shall submit to the Secretary, not later than the date that is 1 year after the date of receipt of such assistance, a report that includes—

(1) an analysis of the effectiveness of the activities for which the entity receives such assistance, as compared to the goals for such activities; and

(2) an analysis of the impact of the project on health care quality and safety.

(b) Requirement to Improve Quality of Care and Decrease in Costs- The National Coordinator shall annually evaluate the activities conducted under this subtitle and shall, in awarding grants, implement the lessons learned from such evaluation in a manner so that awards made subsequent to each such evaluation are made in a manner that, in the determination of the National Coordinator, will result in the greatest improvement in the quality and efficiency of health care.

Appendix B – Additional Information on SHARP Research Focus Areas

This information provides detailed descriptions of the research focus areas and was written by ONC staff.

1. Security for Health Information Technology - This research area addresses the challenges of developing security and risk mitigation policies and the technologies necessary to build and preserve the public trust as health IT systems become ubiquitous.

Health information security is a cornerstone of achieving nationwide exchange and use of electronic health information. Without security there can be no trust. Without trust, we cannot have successful health IT adoption or health information exchange. Without adoption and exchange we cannot achieve the improved health care and health outcomes we want and need. The nationwide achievement of transformational health care improvement through meaningful use of health IT will require the electronic storage and maintenance of an unprecedented volume of data by an unprecedented number of organizational entities. The major challenges requiring breakthrough product solutions include the development of security functions, policies and technology tools that will facilitate increasingly widespread, rapid, and sophisticated, electronic use and exchange of health information while assuring and enhancing individuals' safety and privacy.

This research area is responsive to paragraphs (1), (4), (5), and (6) of the PHSA 3011(a), as added by the Recovery Act, through the following activities:

- Promoting the development and implementation of health information technology solutions that will support the electronic exchange and use of health information in a secure, private manner;
- Promoting the development and implementation of technologies and best practices that enhance the protection of health information by all holders of individually identifiable health information;
- Enhancing the capabilities and functionalities of tools to support privacy and security of individually identifiable health information as it is exchanged and used; and,
- Supporting and enhancing the assurance of privacy needed providers' and patients' widespread acceptance of telemedicine and robust participation in clinical data repositories and registries.

Additional Detail: Information Security is a high priority for the White House. "From now on, our digital infrastructure – the networks and computers we depend on every day – will be treated as they should be: a strategic national asset. Protecting this infrastructure will be a national security priority. We will ensure that these networks are secure, trustworthy, and resilient." [President Barack Obama, May 29, 2009].

Health information security is also a cornerstone of The American Recovery and Reinvestment Act (Recovery Act). "The American Recovery and Reinvestment Act reserves funding to advance the use of health information technology. Protection of patient information will be critical to gaining public acceptance as electronic record keeping becomes more pervasive and accessible through the Internet." [White House Cyber Security Policy Review, May 2009]

Without security there can be no trust. Without trust, we cannot have successful adoption and without adoption we cannot achieve the health outcomes we want and need.

In a paper-based world of health information, securing patients' healthcare records is straightforward and has the benefit of centuries of experience to draw upon. It is self-evidently simple to take a layered approach to security by locking records in filing cabinets which are then placed inside locked rooms, and limiting access only to those who are authorized. Converting this information into digital form requires

the same attention to security, i.e. limiting access to authorized users. However, it raises a different set of challenges that make implementation less simple and less obvious. Mobilizing these data so that they can be used for the improvement of health care raises an entirely new set of security issues. A future world of healthcare information management, in which accurate and complete records about an individual are available anywhere at any time also implies the existence of coherent longitudinal records with necessary access to individuals who need to know creates yet another challenge.

The information security landscape, in general, is dynamic. At the micro level, those responsible for securing sensitive information face a daily influx of new threats. At the macro level, the sources of threats evolve over time. Whereas security threats used to be mainly confined to hackers in it for the sport, today's threat landscape has threats such as those posed by organized crime, with state-based hacking on the rise. Many liken the pursuit of information security to an arms race: continually having to devise new and better defenses against a ceaseless onslaught of ill-intentioned exploits.

Hearings held by the Health IT Standards Committee, a federal advisory committee, highlighted many challenges faced by the healthcare sector, including ones related to how the healthcare lags other sectors in both information security and the development of potential solutions. As a sector, healthcare has faced less security pressure than other sectors, such as defense/intelligence or finance. This is largely attributable to healthcare's lower position on the IT adoption curve. However, the rollout of health IT nationwide will, by definition, increase the pressures rapidly. Never before has there been an intentioned push to adopt IT in a business sector. Other sectors grew organically, when it was clear that IT adoption was, for business reasons, no longer optional. Thus, in other sectors, security preparedness and implementation grew organically as well. Healthcare is preparing to jump start IT: with it, there must be a concomitant effort to build in the security functions that will allow and support rapid adoption in a way that assures safety for patients and other stakeholders. The complexity of related legal, regulatory and risk environment makes this a bigger challenge. Among other solutions, this challenge can be addressed by supporting providers with security tools and education, including security in workforce training, identifying risks and creating strategies to mitigate them, and developing necessary security policies and standards.

One of the challenges in the health information technology industry has been the difficulty of differentiating between "privacy," "confidentiality," and "security." These terms are often used interchangeably but are different and focus on different areas. The Institute of Medicine publication, "Disposition of the Air Force Health Study" (2006) defines these terms as: Health information privacy is an individual's right to control the acquisition, uses, or disclosures of his or her identifiable health data; Confidentiality, which is closely related, refers to the obligations of those who receive information to respect the privacy interests of those to whom the data relate; and Security is altogether different. It refers to physical, technological, or administrative safeguards or tools used to protect identifiable health data from unwarranted access or disclosure. As the adoption of health information technology increases across the country, the security of electronic health records (EHRs) and the health information exchanges is becoming more critical. Privacy is more a policy issue and security is more a technical issues. They both have to work together.

The recent 2009 HIMSS Security Survey suggests that, despite changes to the security and privacy landscape including new legal and regulatory requirements and increasing risk, healthcare organizations have made relatively little progress since the HIMSS 2008 survey relating to a number of important areas of the security environment: maturity level of the organization, completion of risk assessment, planning for response to threats or incidents relating to a security breach, allocation of resources, setting security as a priority and others. The lack of progress in these areas may put health data at a higher risk of exposure in the future, and increase the need for mature security processes and controls. The number of respondents participating in health information exchanges (HIEs) is projected to increase significantly in

the future; with it will create an increased need for data sharing which will add pressure on organizations to be "good business partners" – that is, to be good stewards of what they store and exchange.

Much of the security toolbox is well-known territory, with widely available techniques that can be adapted from other sectors for use in health IT. However, there are several factors that make health IT unique and which are suggestive of a short-term and a longer-term research agenda e.g., very large numbers of very small organizations. Security challenges can be viewed in four major categories: system stability and reliability; cybersecurity; data theft, loss and misuse; and building trust. Technology solutions are required to help institutions address their current challenges, prepare them to comply with the new privacy statutes in the Recovery Act and related upcoming regulation from Health and Human Services (HHS) such as notification of data breaches to the patient (as well as HHS and the public in some circumstances) and provide accounting of all disclosures of protected health information upon patient request (for the three years prior to the request) and address future challenges.

Major topics for research could include:

- Data Integrity and Availability: Identity Management and Future-Proofing focusing on short- and long-term issues
- Data Confidentiality: modeling and simulation focusing on preventive measures
- Consumer access and control: addressing consumer concerns regarding timely access to their own data and how their health data is shared and, potentially, their perceived lack of consumer control
- Data Access: to only those who need access for care delivery;
- Data breaches
- Data stewardship and the ability to assure minimum necessary access and appropriate use of patient data.

Another key aspect of this research topic would be performance measurement and enforcement of policies and technology tools once they are developed which would include clear links between compliance and benefits.

The SHARP for security will need to address short- and long- term challenges. Short term focus is needed to help improve level of trust in health information data and long term focus is needed to sustain this progress.

2. Patient-Centered Cognitive Support - This research area addresses the challenge of harnessing the power of health IT so that it integrates with, enhances and supports clinicians' reasoning and decision making, rather than forcing them into a mode of thinking that is natural to machines but not to people.

Integration with the delivery of care of appropriate health IT to facilitate high levels of clinical performance and effective decision-making poses great challenges for many reasons. Today's clinicians spend a great deal of time and energy searching and sifting through raw data about patients and trying to integrate these data with their general medical knowledge to create an accurate assessment of a patient's situation that is necessary to make patient-care decisions. Such sifting efforts force clinicians to devote precious time and cognitive resources to the details of data and make it more likely that they will overlook some important higher-order consideration. The health care IT systems of today tend to squeeze all cognitive support for the clinician through the lens of health care transactions and the related raw data, without showing how data fit together and which elements are important or unimportant. As a result, an understanding of the patient can be lost amidst all the data, tests, and monitoring equipment. A highly-regarded 2009 study from the National Research Council (NRC) has identified many of these challenges and described the need for innovative approaches that represent significant points of departure from current practice. (See "Computational Technology for Effective Health Care: Immediate Steps and

Strategic Directions," NRC, 2009). Research in this area will identify methods that transform large volumes of data into key elements of information and place in front of clinicians the most important information about that patient at that time, organized in ways that align with how clinicians think.

PHSA 3011(a), as added by the Recovery Act, directs the support of health IT architecture that will support the use of health information in an accurate manner. Additionally, paragraphs (3) and (5) of the same subsection of the statute authorize use of funding appropriated under PHSA Section 3018, as added by the Recovery Act, to disseminate training and information on best practices to integrate health IT into a provider's delivery of care, and to promote the use of clinical data repositories and registries. All of these paragraphs ((1), (3), and (5) of PHSA 3011(a) as added by the Recovery Act) point to longstanding challenges that require new and creative research related to the accurate and effective use of electronic health information to enhance the safety, quality, efficacy, and thus the overall value of care.

Additional Detail: Much of health care is transactional—admitting a patient, encountering a patient at the bedside or clinic, ordering a drug, interpreting a report, or handing off a patient. Yet transactions are only the operational expression of an understanding of the patient and a set of goals and plans for that patient. Clinicians have in mind a conceptual model of the patient reflecting their understanding of interacting physiological, psychological, societal, and other dimensions. They use new findings—raw data—to refine their understanding of the model they are using. Then, based on medical knowledge, medical logic, and mostly heuristic decision making, they make orders (transactions) that they hope will improve the condition of or even cure the (real) patient. A highly-regarded 2009 study from the National Research Council (NRC) has identified many of these challenges and described the need for innovative approaches that represent significant points of departure from current practice. (See "Computational Technology for Effective Health Care: Immediate Steps and Strategic Directions," NRC, 2009).

Today, clinicians spend a great deal of time and energy searching and sifting through raw data about patients and trying to integrate these data with their general medical knowledge to form relevant mental abstractions and associations relevant to the patient's situation. Such sifting efforts force clinicians to devote precious cognitive resources to the details of data and make it more likely that they will overlook some important higher-order consideration.

The health care IT systems of today tend to squeeze all cognitive support for the clinician through the lens of health care transactions and the related raw data, without an underlying representation of a conceptual model for the patient showing how data fit together and which are important or unimportant. As a result, an understanding of the patient can be lost amidst all the data, all the tests, and all the monitoring equipment.

In one compelling vision of patient-centered cognitive support, the clinician interacts with models and abstractions of the patient that place the raw data into context and synthesize them with medical knowledge in ways that make clinical sense for that patient. Raw data are still available, but they are not the direct focus of the clinician. These virtual patient models are the computational counterparts of the clinician's conceptual model of a patient. They depict and simulate a theory about interactions going on in the patient and enable patient-specific parameterization and multi-component alerts. They build on sub-models of biological and physiological systems and also of epidemiology that take into account, for example, the local prevalence of diseases. The use of these models to establish clinical context would free the clinician from having to make direct sense of raw data, and thus he or she would have a much easier time defining, testing, and exploring his/her own working theory. What links the raw data to the abstract models might be called medical logic—that is, computer-based tools that examine raw data relevant to a specific patient and suggest their clinical implications given the context of the models and abstractions.

Computers can then provide decision support—that is, tools that help clinicians decide on a course of action in response to an understanding of the patient's status. At the same time, although clinicians can work with abstractions that keep them from being overwhelmed by data, they must also have the ability to access the raw data as needed if they wish to explore the presented interpretations and abstractions in greater depth.

There are many challenging computer science research problems associated with this vision. Future clinician and patient-facing systems would draw on the data, information, and knowledge obtained in both patient care and research to provide decision support sensitive to workflow and human factors. The decision support systems would explicitly incorporate patient utilities, values, and resource constraints (e.g., cost-effectiveness analysis, value of information, and so on). They would support holistic plans, intentions, and multiple decision makers. They would allow users to simulate interventions on the virtual patient before doing them for real. These decision support systems would have transactions built into them to help users carry out orders, in contrast to today's systems in which decision support is commonly an add-on to systems and is designed primarily for transaction processing. Rather than having data entered by clinicians into computer systems, the content of clinical interactions would be captured in self-documenting environments with little or no additional effort on the part of the clinicians. (That is, an intelligent, sensor-rich environment would monitor clinical interactions and reduce sensor input to notes that document the medically significant content of those interactions.)

In addition to the research challenges related to modeling the virtual patient and biomedical knowledge, there are probable challenges in modeling and supporting multiplayer decision making (e.g., involving family, patient, primary care provider, specialist, payer, and so on). Techniques to interconnect the components are likely to be equally challenging.

Major topics for research could include:

- Creating models that support dynamic abstraction of clinical information
- Techniques for parsimonious information display information that simplifies, while capturing essential features of a clinical decision problem
- Understanding decision making under stress and time pressure, and its implications for cognitive support
- Communication to clinicians, addressing message content and delivery, that blends with workflow
- Methods to support decisions that involve multiple stakeholders, taking into account their preferences and utilities
- Methods for minimizing and simplifying, when it is necessary, manual data input by clinicians

3. Healthcare Application and Network Platforms - This research area focuses on the development of new and improved architectures that will leverage benefits of today's architecture and focus on the flexibility and scalability needs for the future to address significant increase in capture, store and analysis of data. This research will improve upon current architectures by enabling greater application capability and flexibility, as well as a higher level of data service integration. It will support envisioned future development of the Nationwide Health Information Network (NHIN).

Health care is inherently a distributed, information-intensive enterprise. As the volume of data captured, stored, and used electronically increases, the nation will witness a concomitant increase in the need for architectures supporting applications and resources that can capture, store, and analyze that data. Historically, there has been a distinction between the applications and operating systems running on a computer, and the services and networks available through the internet. That distinction is increasingly

artificial. People can now access the same data through multiple devices, across multiple platforms. Email, once only accessible through specialized applications running on a desktop machine, now can be used on mobile devices, through the web, on applications running on machines or through voicemail translation. Data liquidity in which the data follows the patient requires application and network "liquidity" in which the applications and networks have similar flexibility. Standards-based, modular, flexible, and innovative architectures to provide healthcare providers, research, patients, and others with the data and application services that they need will be a key component of assuring that data liquidity is appropriately supported by application services. Research in this area will promote health IT adoption and meaningful use through the development of more flexible, modular, "swappable" tools that ensure that clinicians are using the best tool available to support their work.

PHSA 3011(a)(1), as added by the Recovery Act, authorizes support of health IT architecture that will support "the nationwide electronic exchange and use of health information in a secure, private, and accurate manner". This research focus specifically supports the development of new and improved architectures and technology infrastructure needed to achieve the goals outlined in the plan for health IT by the National Coordinator in support of PHSA 3001(c)(3), as added by the Recovery Act, and to support measures for determination of meaningful use of health IT by providers over time (required by Social Security Act (SSA) Sections 1848(o) and 1866(n), as added by Title IV in Division B of the Recovery Act).

Additional Detail: Managing data across a distributed, information intensive enterprise will require novel applications and resources that can capture, store, and analyze that data. As the volume of electronic data increases, we will need modular, extensible and innovative applications and services that provide the building blocks of integrated data services. In the past, applications have been of single purpose or linked to a particular operating system or network service. In the future however, the distinction between where an application or service resides will likely be dynamic. People will likely be able to access the same data through multiple devices across multiple platforms. These services or applications should be capable of being assembled dynamically to support novel, and innovated ways of capturing, storing, and analyzing data.

Data liquidity in which the data follows the patient requires application and network "liquidity" in which the applications and networks have similar flexibility. Standards-based, modular, flexible, and innovative approaches to provide healthcare providers, research, patients, and others with the data and application services that they need will be a key component of assuring that data liquidity has the accompanying application services as well.

We anticipate that this research can advance the field in three ways.

- **Network platforms for data analysis and services -** As we accumulate large amounts of data, having web-based services to capture, store and analyze data will be critical. Cloud computing, service-based architectures, and novel ways of integrating across wide area networks the flow and analysis of data will provide users with dynamic and configurable resources across the web, the grid, or the cloud.

  Major topics for research could include:
  - Dynamic assembly of services and resources, based on the nature of the data and the question being asked
  - Creation of architectural frameworks that can support a layered approach to managing data transport, semantics, and application services
  - Development of standards-based network services to support data capture, storage and analysis

- Comparison of alternative architectures to support data capture, storage and analysis

- **Modular platforms for application development -** While network services provide a dynamic and configurable approach to large data services, there is a similar need for smaller-scale, but equally configurable and modular development platforms for users. Creating application building blocks that can be configured or assembled by a user to capture, store, and analyze data at a smaller scale will also be important.

  Major topics for research could include:
  - Configurable open-source platforms and development environments that will support modular software development
  - Development of standards-based, interoperable modules that can dynamically process and route data analysis functions

- **Integration of data services across the spectrum -** Although the scale of network platforms and application platforms are different, they both provide a modular approach to analyzing data. Ultimately, integration of application building blocks with the network building blocks provide an innovative platform in which the location or platform of the analysis is not important. Users will chose the right application for the thing that it does, rather than for the location on the web, the ability to run on a particular operating system, computer, or mobile device. In this scenario, not only does the data follow the patient, but the applications and services do as well.

  Major topics for research could include:
  - Use of existing standards (or identification of new standards) for interoperability between data services
  - Demonstration and evaluation of multi-tiered analysis platforms
  - Object-oriented services for data and applications that integrate and organize data (and services) around patient needs

4. Secondary Use of EHR Data - This research area focuses on strategies to enhance the use of health information technology in improving the overall quality of health care.

Widespread implementation of EHRs and related health IT will result in the steady accumulation of large amounts of patient data that can be leveraged to improve the quality, safety and efficiency of care and extend public health and research. EHR data can be analyzed by providers, health plan and governments to identify best care practices and assess quality of care according to those practices. EHR data can also be applied to determine the relative clinical effectiveness of different interventions, e.g., medications, devices and procedures. EHR data may be used to determine if medications or devices are posing post-market risks to patients. Finally, EHR data can be used to accelerate clinical research; for example, by serving as a source of phenotype data in genome association studies. As important as the potential applications are, and as straightforward as they may seem, several challenges requiring breakthrough solutions confront each of these uses. The challenges requiring breakthrough solutions include methods for addressing incomplete and inconsistent data and for extracting coded data from unstructured text. Research in this area will promote health IT adoption and meaningful use through new methods that place greatly improved computational and analytical tools in the hands of researchers and practitioners.

PHSA 3011(a), as added by the Recovery Act, directs the Secretary to invest in the infrastructure necessary to allow for and promote the electronic exchange and use of health information for each individual in the United States consistent with the goals outlined in the strategic plan developed by the

National Coordinator. PHSA 3001(c) (3), as added by the Recovery Act, directs that the National Coordinator shall, "in consultation with other appropriate Federal agencies (including the National Institute of Standards and Technology), update the Federal Health IT Strategic Plan (developed as of June 3, 2008) to include specific objectives, milestones, and metrics with respect to" a following list of 8 specific areas. The current Federal Health IT Strategic Plan (developed as of June 3, 2008), as referenced in the statute, advances "secondary use" as a key mode of information technology use to transform health care. This is consistent with, and will be updated and expanded upon pursuant to the direction of PHSA 3001(c)(3)(i), (vii) and (vii), as added by the Recovery Act, to add to the updated strategic plan such objectives, milestones, and metrics with respect to:

- *(Reference: PHSA 3001(c)(3)(i))* – the electronic exchange and use of health information and the enterprise integration of such information.
- *(Reference: PHSA 3001(c)(3)(vii))* – strategies to enhance the use of health information technology in improving the quality of health care, reducing medical errors, reducing health disparities improving public health, increasing prevention and coordination with community resources, and improving the continuity of care among health care settings.
- *(Reference: PHSA 3001(c)(3)(viii))* – the specific plans for ensuring that populations with unique needs, such as children, are appropriately addressed in the technology design, as appropriate.

Additional Detail: The nation-wide implementation of interoperable electronic health records will result in the steady accumulation of large amounts of patient data. This data will be distributed across a wide range of provider organization databases, health information exchange repositories and public health agencies. This data can be potentially used for analyses of aggregate data to improve the quality, safety and efficiency of care and extend public health and research. Potential leverage opportunities are described below.

Care performance. These data can be applied by providers, health plan and governments to define best care practices and assess care according to those practices. Data can be used to identify care variations across providers and regions and identify those care practices that lead to better outcomes. Moreover the data can be used to automatically report quality measures, easing the reporting burden on the provider and extending the range of measures that can be gathered.

Comparative effectiveness. Electronic health record data can be applied to determine the relative clinical effectiveness of different interventions, e.g., medications, devices and procedures. For example, analyses will enable the comparison of cohorts of patients that have received different treatments to identify which treatments provide better outcomes. Since the databases will have large numbers of patients and cover the diversity of the country, these analyses can determine if there are variation in outcomes across different socio-economic variables

The use of EHR data provides "real world" assessments which can be more informative than assessments that occur during clinical trials.

Post-market surveillance. Electronic health record data may be used to determine if medications or devices are posing post-market risks to patients. This use might enable earlier detection of problems and permit analyses to determine if the risk varies by different types of cohorts. This use might also enable the identification of cohorts for whom the intervention benefit is much more significant than the realized risk.

Clinical research. Electronic health record data can be used to accelerate clinical research. These data can be extracted from EHRs and, with patient consent, transmitted to research databases reducing the data collection burden of the investigator and the patient's providers. In addition, the electronic health record can be used to notify the patient and their provider that the patient may be eligible for a clinical trial

These areas of secondary use of electronic health record data appear to hold great promise. However several areas require research for this potential to be realized.

Major topics for research could include:

- Strategies, heuristics and methods to compensate for inconsistent, conflicting and incomplete data
- Methods for retrospectively and prospectively creating “in silico” cohorts of study controls and intervention populations

Technical approaches and governance mechanisms for managing analyses, intellectual property and patient privacy for

Appendix C – Suggested Content for Letter of Intent to Apply

Applicants are requested, but not required, to submit a Letter of Intent to apply for this funding opportunity; the deadline for the letter of intent is January 4, 2010 at 11:59 p.m. ET. Letters of intent must be sent electronically to the project officer Wil Yu, at Wil.Yu@HHS.gov.

This Letter of Intent is a preliminary, non-binding indication of an organization's intent to submit an application and should contain the information in the following template:

Date

David Blumenthal MD, MPP
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. Blumenthal,

(Name of organization submitting the letter) intends apply for the Funding Opportunity number ##-###, Strategic Health IT Advanced Research Projects program that is part of the American Recovery and Reinvestment Act of 2009, Title XIII – Health Information Technology.

Be sure to include the following information:

- *Name, address, and telephone number of the Principal Investigator.*
- *Names of other key personnel*
- *The research area to be addressed by the application (specifically, one of the four areas listed in the FOA)*
- *Other institutions/organizations that will be part of the application*

Sincerely,

Name
Title
Organization
Division (if applicable)
State
Address
Phone
Fax Number
Email

Appendix D – Required Documents for SHARP Applications

- Letter of Intent to Apply (See Appendix C Suggested Content for Letter of Intent) - The letter of intent must be received by January 4, 2010. [optional]

Application Package

- Project Abstract (Section IV, Part 3b)
- Project Narrative (Section IV, Part 3c)
    - Research Topic, Vision Statement, and Key Challenges (3-5 pages)
    - Proposed Approach (13-18 pages)
    - Plan for Transitioning Appropriate Research Results into Practice (3-4 pages)
    - Committees and Stakeholder Involvement (2-3 pages)
    - Project Management (2-4 pages)
    - Evaluation (1-2 pages)
    - Organizational Capability (3-5 pages, exclusive of biosketches and organizational chart)
- Literature Cited (Section IV, Part 3d)
- Work Plan (Section IV, Part 3e)
- Letters of Commitment from Key Participating Organizations and Agencies (Section IV, Part 3f)
- Budget Narrative/Justification (Section IV, Part 3g)
- Additional forms within the SF-424 R&R Family – Application forms are available through Grants.gov. You may download the application package, complete it off-line, and the upload and submit the application via the Grants.gov site. Online instructions are embedded in the form fields—simply scroll your mouse over the field. Applicants may also take advantage of the online tutorials, FAQs, and resources available online at www.Grants.gov.
    - Application for Federal Assistance (SF 424 R&R)
    - Research & Related Budget
    - Research & Related Sub-award Budget Attachment(s) Form
    - Project/Performance Site Location(s)
    - Research & Related Senior/Key Person Profile
    - Assurances for Non-Construction Programs (SF-424B)
    - Disclosure of Lobbying Activities (SF-LLL)
- Conflict of Interest Certification (Appendix E)
- Additional Appendix Material (optional) (Section IV, Part 3h)

Appendix E – Conflict of Interest Certification Template

CONFLICT OF INTEREST CERTIFICATION

American Recovery and Reinvestment Act of 2009:
Strategic Health IT Advanced Research Projects

DHHS Office:	Office of the National Coordinator for Health Information Technology
CFDA Number:	93.728
Funding Opportunity Number:	HHS-2010-ONC-TR-005

Legal Applicant Name: _____

Legal Vendor Name: _____

My signature below certifies that, in submitting the preliminary application for the above referenced award, there are no potential, real or perceived conflicts of interest relative to the anticipated collaboration between our organization _____ and the health IT vendor _____.

I also acknowledge my responsibility to disclose any future potential, real or perceived conflicts of interest, between our organization _____ with the health IT vendor _____ should the attestation within this certification change in the future.

Organization Authorized Representative	Vendor Authorized Representative
Position of Authorized Representative	Position of Authorized Representative
Date	Date

Appendix F – Recovery Act-Required Performance Measures

Recovery Act-Required Performance Measures

To assist in fulfilling the accountability objectives of the Recovery Act, as well as the Department's responsibilities under the Government Performance and Results Act of 1993 (GPRA), Public Law 103-62, applicants who receive funding under this program must provide data that measure the results of their work. The following are required measures for awards made under the Recovery Act:

Objective	**Performance Measures**	**Data the recipient provides for 3-month reporting period**	**Description (Plain language explanation of what exactly is being provided)**
Recovery Act: Preserving jobs	Number of jobs saved (by type) due to Recovery Act funding.	a) How many jobs were prevented from being eliminated with Recovery Act funding during this reporting period? b) How many jobs that were eliminated within the last 12 months were reinstated with Recovery Act funding?	An unduplicated number of jobs that would have been eliminated if not for Recovery Act funding during the three-month quarter. Report this data for each position only once during the project period. A job can include full time, part time, contractual, or other employment relationship.
Recovery Act: Creating jobs	Number of jobs created (by type) due to Recovery Act funding.	How many jobs were created with Recovery Act funding this reporting period?	An unduplicated number of jobs created due to Recovery Act funding during the three-month quarter. Report this data for each position only once during the award. A job can include full time, part time, contractual, or other employment relationship.