OMB Number 0990-XXXX
Expiration Date 05/31/2010

Health Information Technology Research Centers of Excellence (TRCE)

Application Form

Application and Submission Information

Address to Request Application Package

Application materials will be available for download at http://www.grants.gov. ONC is requiring full applications for all announcements to be submitted via electronic mail. Applicants will be able to download a copy of the application packet, complete it off-line, and then submit the application electronically via email.

APPLICATIONS WILL NOT BE ACCEPTED THROUGH ANY WEBSITE, AND WILL NOT BE ACCEPTED THROUGH PAPER MAIL, 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 C, BELOW.

Applications procedures:

- Applicants must access the electronic application for this program via http://www.grants.gov. Applicants must search the downloadable application page by the Funding Opportunity Number (HHS-2010-ONC-TR-005) or CFDA number (93.728).
- All lead applicants should have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number and register in the Central Contractor Registry (CCR) (for further information see section IV.B.2 below). Applicants should allow a minimum of five days to complete the CCR registration. Although not required to process preliminary applications, lead applicants who do not already have a DUNS number and/or are not registered in CCR should do so as soon as possible. As there is no fee to complete these processes, applicants should not wait to receive the results of the preliminary application review before taking these steps.

- Applicants must submit all documents electronically, including all information included on the SF424 and all necessary assurances and certifications.
- The applicant's application must comply with any page limitation requirements described in this Program Guidance.
- After the application is electronically submitted, the applicant will receive an automatic email notification from the email address that demonstrates the email was received. This notification does **not** provide assurance that the application was complete, only that the email was received.
- After ONC reviews the email submission, a return receipt will be emailed to the applicant contact indicating the files that were received and able to be successfully opened and read. Due to volume of applications received, this receipt may not be available for several days; applicants are strongly encouraged to submit applications as far in advance as possible if they wish to receive confirmation of receipt prior to the deadline. Organizations applying for federal grants will need to be registered with the Central Contractor Registry (CCR). Applicants can register with the CCR online and it will take about 30 minutes (http://www.ccr.gov). If the applicant has already registered with CCR but have not renewed their registration in the last 12 months, they will need to renew their registration at http://www.ccr.gov.

Key Contact for Applications:

Inquiries should be addressed to:
Wil Yu
200 Independence Way, 7th Floor
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Washington, DC 20201
Email: Wil.Yu@HHS.gov
202-690-5920

Content and Form of Application Submission

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 application 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 listed in Section VII, Agency Contacts, below.

Letters of intent must be sent electronically to:

Wil Yu
U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology

Email: Wil.Yu@HHS.gov

2. Letter of Intent Content Guidelines

Applicants may submit a Letter of Intent to apply for this funding opportunity; the deadline for the Letter of Intent is January 4, 2010. This Letter of Intent should contain the following:

- Number and title of this funding opportunity
- Name, address, and telephone number of the primary point of contact
- Names of other key personnel
- Participating collaborators

3. DUNS Number

The Office of Management and Budget (OMB) 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. 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.

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 .

4. Project Abstract

Applicants shall include a one-page abstract (no more than 1000 words) of 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):

- Project Title
- Applicant Name
- Address
- Contact Name
- Contact Phone Numbers (Voice, Fax)
- E-Mail Address
- Web Site Address, if applicable

5. 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. A fifty page limit applies to applications proposing to address up two areas of research focus. 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 Center 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 Center 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 Center'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 TRCE Federal Steering Committee (FSC), and ONC. (2-4 pages)

Evaluation. Recipients will be required to maintain information relevant to achieving the milestones specified in Section II, Part 3, 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 Center'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)

6. Work Plan

The Project Work Plan should reflect and be consistent with the project narrative and budget and should cover the budget years (total of 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. (1-2 pages)

7. 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.

8. Budget Narrative/Justification

Each application should include a detailed budget for the first two years of funding requested and a detailed summary of the request for all four years. The applicant may request up to $15 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.

- 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

The core budget may not exceed $15M, inclusive of direct costs. Final budgets will be negotiated with each successful applicant.

A combined multi-year Budget Narrative/Justification, as well as a detailed Budget Narrative/Justification for each year of potential grant funding is required. Please note that when more than 33% of a project's total budget is listed in the contractual line item, detailed budget narratives/justifications must be provided for each contractor for each year of potential grant funding.

Appendix B – Additional Information on TRCE Research Focus Areas

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 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 center of excellence 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 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.

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.

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 are necessary to achieve electronic exchange and use of health information in a secure, private and accurate manner.

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.

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 needed to advance toward the goals outlined in the plan for health IT developed by the National Coordinator pursuant to PHSA 3001(c)(3), as added by the Recovery Act, and to support increasingly stringent 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 information technology 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.

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 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

There are several, substantive potential uses of electronic health record data for population health, care assessment, post-market surveillance and clinical research.

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 ##-###, Technology Research Centers of Excellence 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