INVENTORY AND EVALUATION OF CLINICAL RESEARCH NETWORKS

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SUPPORTING STATEMENT A

Request for OMB Clearance
Title: Inventory and Evaluation of Clinical Research Networks (IECRN)
(NCRR)

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A. Justification

A.1 Circumstances Making the Collection of Information Necessary

In May 2002, Elias A. Zerhouni, M.D., Director of the National Institutes of Health, (NIH) launched the Roadmap initiative for medical research in the 21st century. The purpose was to identify major opportunities and gaps in biomedical research that no single institute at NIH could tackle alone, but that the agency as a whole must address to make the biggest impact on the progress of medical research. The translation of basic research into clinical practice, at the heart of NIHs mission, requires that basic research discoveries be quickly transformed into drugs, treatments, or methods for disease prevention. An important issue in the enhancement of the clinical research system is the need to develop new partnerships between research and organized patient communities, community-based health care providers, and academic researchers. This includes building integrated networks of academic centers linked to a qualified body of community-based health care providers who care for sufficiently large groups of patients interested in working with researchers to quickly develop, test, and deliver new interventions. This also requires new paradigms in how clinical research information is recorded, new standards for clinical research protocols, modern information technology platforms for research, new models of cooperation between NIH and patient advocates, and new strategies to re-energize our clinical research workforce.

The data collection proposed under this clearance request is a revision of a component of a previously approved collection for the Inventory and Evaluation of Clinical Research Networks (IECRN - **OMB** #0925-0550 Expiration: 07/31/08), a Roadmap project addressing the “re-engineering” of the clinical research enterprise. This information collection is authorized by 42 USC 241 and 282(b). Re-engineering the

Clinical Research Enterprise is intended to address pressing needs by promoting the better integration of existing clinical research networks, encouraging the development of technologies to improve the assessment of clinical outcomes, harmonizing regulatory processes, and enhancing training for clinical researchers.

To accomplish these goals and to measure improvements in the clinical research enterprise, the NIH needed to know the variety, extent, and operating status of existing clinical research networks funded by NIH, by other public agencies, and by the private sector. To promote better integration and improvement of network capabilities, the NIH sought to develop an inventory of clinical research networks and to make this information available to the clinical research community. The inventory is a repository of information on clinical research networks worldwide and as a reference for investigators involved in clinical research.

This request addresses extending data collection using the Core Survey, a brief questionnaire soliciting information from networks to include in the inventory posted on the web (https://www.clinicalresearchnetworks.org/default.asp.) Beginning in May 2005, during the first phase of the IECRN project, data were collected from approximately 250 networks. In 2006 approximately 15 additional networks were added to the inventory, and in 2007 there were approximately 8. This request is to extend the currently approved collection to continue to use the same instrument to collect information from new and newly identified research networks so that the data in the inventory are current and up-to-date. Because there are many factors that may influence the identification of existing networks and the creation of new networks, we cannot assume that there will be 9 or fewer networks added to the inventory on an annual basis. In addition, networks currently participating in the inventory are requested annually to review their data and provide updates so that the information in the inventory – known as the “network profile” – is current and accurate. There will be no statistical analysis of these data.

The *Core Survey* is used to collect information on a continual ongoing basis from networks identified or newly formed since the first data collection approval period. While active identification and recruitment of networks is no longer occurring in this phase of the project, Westat continues to utilize survey procedures intended to maximize response rates. For example, networks expressing an interest in joining the inventory (through the “Add Your Network” link on the website or otherwise) receive a response within 5 calendar days. If a completed survey is not returned within three weeks, Westat will make a follow-up phone call or email to offer assistance, to determine if the survey was sent to the appropriate respondent, and to encourage response. The survey was designed to be easy-to-read with simple instructions, and is accompanied by a description of the purpose of the survey, emphasizing the goals of the NIH Roadmap, and presented as an opportunity for clinical research networks to promote their research networks. In addition, a toll-free telephone number and email address has been set-up for respondents with questions. The survey is provided to respondents as a writable PDF file, with data fields that can be completed electronically; the survey can then be submitted to Westat either as an email attachment or printed and returned by fax or mail.

Networks can update profile information at any time, by clicking on the “Provide Update” button at the bottom of each network profile page on the web site. The date that information was last updated is provided at the top of each network profile. On an annual basis, networks are sent a reminder email and asked to electronically review the information in their network profiles to ensure that it is accurate and complete. Respondents can either indicate that there are no changes or enter any revisions into the text boxes associated with each field. Our past experience shows that many of the networks do not actively respond to this annual reminder. Our records for 2007 indicate that, of the 230 networks from which an update was requested, 56 (24%) replied to confirm that their information was still correct. Of the remaining 174 networks, 49 (28%) responded with changes. Westat follows up to resolve any undelivered update emails that are received, so that the update email can be sent to the correct contact.

A.2 Purpose and Use of the Information

The original data collection for the IECRN project identified and surveyed clinical research networks to obtain data for two purposes: (1) to create a web-based inventory of clinical research networks that can be accessed by the clinical research community and the general public (*Core Survey* data collection) and (2) to prepare a detailed description of existing network practices from a sample of identified networks (*Descriptive Survey* data collection). The current request is to continue collecting data for the first purpose only (*Core Survey*).

This survey data collection is exempt from IRB review. See Attachment 1 for a copy of the IRB letter of exemption. The instrument known as the *Core Survey* will be used to collect eligibility information to confirm that the respondent fits the IECRN project definition of a clinical research network, plus basic characteristics about each identified clinical research network to be included in the web-based inventory. The information for the inventory database includes the network's name, address, contact information, funding sources, age, geographic coverage, size, composition, and populations and diseases of focus. Permission to post the network's data in the web-based public inventory will be requested, and only those networks that agree will have their information posted. Currently the inventory includes network profiles for 270 clinical research networks. While this number is believed to represent most of the existing networks, some networks have not yet been identified, are unaware of the existence of the inventory, or are newly formed since the original data collection occurred. In addition, each network is requested annually to update the information posted to ensure that the inventory is complete and accurate. See Attachment 2 for a copy of the *Core Survey*.

Westat, the primary contractor, is responsible for data collection, quality control, and web site maintenance. The eligibility confirmation information from the *Core Survey* will be used by Westat only to

confirm that the network should be included in the web-based public inventory database. Fundamental information and network attributes is posted to the web-based public inventory database if the network gives approval for this posting. The information can then be used by clinical researchers and other clinicians to identify research networks that are conducting research in a particular field, with specific patient populations, or with organizational structures that may be appropriate for collaboration or integration of research interests. The information can also be used by NIH and other agencies to monitor the overall research network universe and identify underserved areas for which new initiatives might be justified. A web link will be provided to each network's own web site so that users can access any information that the network makes publicly available. If the clinical research network reported that they conduct clinical trials, a link to the web site for *ClinicalTrials.gov* appears on its profile next to the results for Types of Studies.

Active identification and recruitment of research networks was suspended following the data collection phase in 2005. Through efforts to disseminate information about the IECRN project and the availability of the website (including its public web presence, primacy as a Google search term, and presentations at scientific conferences), many members of the research community are aware of the existence of the inventory. The approximately 23 networks that completed the *Core Survey* in 2006 and 2007 usually contacted Westat, by phone, email, or through the "Add Your Network" link on the website, to request more information about joining the inventory.

To keep the inventory information current, Westat sends a customized reminder email (see Attachment 3: Annual Update Reminder) to each network requesting confirmation that their online profile information is accurate and complete. To update the profile, the network is required to do the following:

- Review the contents of their network profile (the link is included in the email);

- Click on the “Provide Update” button at the bottom of the profile;
- Either indicate that there are no changes or enter any revisions into the text boxes associated with each field;
- Submit their response electronically by selecting the “Request Update” button on the bottom of the form.

Once the network has completed these steps, Westat verifies the authority of the respondent, and makes the requested updates (if applicable) to the database. Westat follows up to resolve any undelivered update emails that are received, so that the update email can be sent to the correct contact.

The IECRN project website has recently (Fall 2007) begun development to update the inventory website to be more user friendly, to have a more relevant name, a more appealing logo, and to emphasize the focus on the online inventory rather than the IECRN project. The new name of the website is *Networks for Clinical Research*. The primary focus of the website is searching for network information, and this feature has been prominently incorporated on the home page.

The existence of the inventory has prompted the practice-based research network (PBRN) community to initiate efforts to streamline and coordinate the inventory data collection process so PBRNs do not have to provide similar information both to the Networks for Clinical Research Inventory and to the inventory of PBRNs supported by the Agency for Healthcare Research and Quality (AHRQ). Beginning in fall 2007, PBRNs are no longer required to submit information to the Networks for Clinical Research Inventory; information from the AHRQ data collection is provided annually to Westat, who then updates the inventory database for those PBRNs.

A.3 Use of Improved Information Technology and Burden Reduction

The *Core Survey* is provided to respondents as a writable PDF file, with data fields that can be completed electronically; the survey can then be submitted to Westat either as an email attachment or printed and returned by fax or mail. This helps reduce burden by making it easier for respondents to complete and submit the questionnaire. Once the information is received from the network respondent, Westat adds the data to the inventory database.

The process for requesting *annual updates* to network profiles involves contacting each network representative by email and requesting a review and update of the network information. The network contact person is provided with a link to their network profile in the email, and is instructed how to submit the revised information. There is also the option of confirming that the information is accurate and that no profile updates need to be made. We estimate it takes 5-10 minutes for the network respondent to review the network profile and indicate revisions. Once the information is received from the network respondent, Westat makes the requested changes to the inventory database.

A.4 Efforts to Identify Duplication and Use of Similar Information

The NIH and its contractor, Westat, have determined that no other database of clinical research networks exists. For the initial data collection, the NIH confirmed through each respective Institute and Center that no group at NIH maintains such an inventory. Westat also confirmed through internet searches and contacts with senior leaders of clinical research networks that no comprehensive clinical research network inventory was known to exist.

For the first phase of data collection (May 2005 – present), the NIH and Westat used to the extent possible all current sources of information to help assemble a preliminary inventory. This included asking members of the trans-NIH Roadmap committee to review its Institute's funded portfolio to identify every program that appears to be a clinical research network, visiting websites of all NIH Institutes and other government agencies that sponsor health research to identify programs that could be clinical research networks, searching recent medical literature, conducting a general internet search to identify websites that use terminology that suggests that an organization might be a clinical research network, and circulating the names of potential network to the trans-NIH committee, the network leaders who served on Westat's Advisory Panel, and the other investigators involved in Roadmap-funded network initiatives to determine if any clinical research networks may have been overlooked. From the original list of over 700 groups and programs that were potentially clinical research networks, the Westat team reviewed all available information to determine if there was evidence that the group or program qualified as a clinical research network based on the project eligibility definition. Using information that was publicly available, the Westat team reduced the number of possible clinical research networks to approximately 300. The next step was to directly contact the networks to verify this information through the *Core Survey*.

To avoid duplication, AHRQ (David Meyers) and NCRR/NIH (Jody Sachs) met in the summer of 2007 to discuss ways to reduce the burden on primary care PBRNs by eliminating the need to complete two questionnaires (one for the IECRN inventory and one with similar information for the AHRQ registry). It was determined that the IECRN Core survey questions could be incorporated into the annual AHRQ registry that is completed by PBRNs. The 2007 registry was updated with the IECRN questions and distributed by AHRQ in August 2007 to the primary care PBRNs. AHRQ provides Westat will the relevant information needed to update the network profile residing in the Networks for Clinical Research Inventory.

A.5 Impact on Small Businesses or Other Small Entities

The collection of information for the clinical research network inventory will not have an impact on small businesses or other small entities. Information will be collected only from the leadership of the clinical research networks. Leaders of these networks are typically from universities and academic medical centers, other large medical centers, and other large research organizations.

A.6 Consequences of Collecting the Information Less Frequently

The *Core Survey* is used to collect information on an *ongoing basis, as needed*, from networks newly identified or newly formed since the first data collection approval period. While active identification and recruitment of networks is no longer part of this phase of the project, Westat continues to utilize survey procedures intended to maximize response rates. In addition, to ensure that information in the inventory on the public web site is current and accurate, Westat *annually* sends a customized reminder email to each network in the inventory requesting confirmation that their online profile information is up-to-date. It is important to request that networks provide updates on an annual basis rather than less frequently as the information is publicly available and the scientific community and leadership will need reliable data on the current status of clinical research networks. Networks can update profile information at any time, however, and the date of the last update is on the network profile page.

The information collected by the IECRN project is essential to Dr. Zerhouni, the Director of the National Institutes of Health, and others in the clinical research community, since it provides descriptive information on the existing clinical research network infrastructure that can be utilized to increase the productivity and efficiency of NIH

funding to expedite translation of basic research findings into treatments for human disease.

If this information collection does not continue, or is conducted less frequently, the NIH will be hindered in its goal of re-engineering the clinical research enterprise to make it more productive and efficient. Updated information is needed to keep the web site relevant, and without accurate and complete information, the NIH will not be able to reach out to clinical research networks to facilitate their interaction and collaboration, to identify and encourage the adoption of best practices, and to increase openness to greater participation by clinicians and communities. Since Re-engineering the Clinical Research Enterprise is one of the three key focus areas of the NIH Roadmap, the Roadmap initiative cannot achieve its goals without the availability of the information collected in this project.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection fully complies with all the guidelines of 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult

Outside the Agency

Under the provisions of Section 3506(c) (2) (A) of the Paperwork Reduction Act of 1995, the National Center for Research Resource (NCRR), the National Institutes of Health (NIH) submitted to the Office of Management and Budget (OMB) a request for review and approval for continuation of the collection of new information for the Inventory and Evaluation of Clinical Research Networks – OMB #0925-0550 Expiration: 07/31/08. This proposed information collection was

previously published in the Federal Register on March 24, 2008, Vol. 73, No. 57, page 15530, and allowed 60-days for public comment. No public comments were received.

A.9 Explanation of Any Payment or Gift to Respondents

There will be no payment or gifts to respondents for the IECRN *Core Survey*.

A.10 Assurance of Confidentiality Provided to Respondents

The requested information contains network identifiable information. Information describing the IECRN project and the purpose of the inventory accompanies the *Core Survey*, indicating that the *Core Survey* asks the clinical research network's representative for permission to post the network information on the public website. The network will not be penalized should it decide not to grant that permission.

Network information collected from the *Core Survey,* and with permission of the network, is included in the web-based inventory of clinical research networks that can be accessed by the clinical research community and the general public on a public web-site. The information will be network specific and not PI or protocol specific. Individual research protocols will not be listed in the inventory, but there will be a web link to the network for interested parties who wish to seek additional information about a particular network. This data collection effort has been deemed exempt as outlined in the letter from the NIH Privacy Officer. See Attachment 4 for a copy of the letter from the NIH Privacy Office.

A.11 Justification for Sensitive Questions

No sensitive information is being collected. These surveys contain no questions about sexual behavior and attitudes, religious beliefs, salaries, social security numbers, reproductive decisions, use and abuse of alcohol and drugs, psychological problems, or questions about a third party without their knowledge.

A.12 Estimates of Burden Hours and Costs

We have continued to use the *Core Survey* as networks are newly identified. In 2006 we added approximately 15 networks to the inventory; in 2007 we added approximately 8. We estimate that each respondent of the *Core Survey* spends 15 minutes reading the introductory materials and instructions and completing the instrument. These time estimates are based on informal pretests with 9 or fewer individuals, conducted for the original collection.

For the annual updates, we estimate that the network contact spends less than 10 minutes reviewing the instructions and the existing profile information. The annual update request is made to all networks with profiles in the inventory (with the exception of practice-based research networks as explained above).

The respondent population for the *Core Survey* has been physicians, research directors, or other health professionals associated with the network. The hourly rates were based on median hourly wage estimates as reported by the U.S. Department of Labor, Bureau of Labor Statistics, in the November 2006 National Occupational Employment and Wage Estimates Report for Healthcare Practitioners and Technical Occupations (http://www.bls.gov/oes/current/oes_29he.htm). The total annualized cost to respondents is estimated to be $3,619, based on an average of $70.00 per hour for 20 *Core Survey* responses from physicians, and $70.00 per hour for 280 *annual update* responses from physicians (the P.I. or other network contact).

Table A.12-1 shows the estimates of annual hour burden for the proposed survey and the annual update. Table A.12-2 presents the annualized costs to respondents.

Table A.12-1 Estimates of annual burden hours

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response (Hours)	Annual Burden Hours
Core Survey				
Principal Investigator	20	1	15/60	5
Annual Update				
PI/network contact	280	1	10/60	46.6667
Total				**51.7**

Table A.12-2 Annualized cost to respondents

Type of Respondents	Annual Burden Hours	Hourly Wage Rate	Respondent Cost
Core Survey			
Principal Investigator	5	$70.00	$350.00
Annual Update			
PI/network contact	46.6667	$70.00	$3,266.67
Total			**$3,616.67**

A.13 Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no capital or start-up costs, and no maintenance or service cost components to report.

A.14 Annualized Cost to the Federal Government

The total cost to the Federal Government for the proposed survey is estimated to be approximately $16,588 per month, representing an annualized cost of about $ 199,055 per year (direct and indirect costs), as presented below in Table A.14-1.

Table A.14-1 Estimate of annualized cost to the federal government

Salaried Labor	72,420
Computing	8,021
Copying	724
Telephone	716
Supplies	724
Printing	724
TOTAL (direct costs)	**$ 83,329**
Estimate of Other Total Annual Cost Burden:	**$ 115,726**

These estimates are from a contract with Westat, a contract research organization, who will provide labor and other costs necessary to carry out data collection, receipt control, data processing activities, and web site maintenance. This contract expires on February 28, 2010.

A.15 Explanation for Program Changes or Adjustments

The data collection proposed under this clearance request is a revision of a previously approved collection for the Inventory and Evaluation of Clinical Research Networks (IECRN - OMB #0925-0550 Expiration: 07/31/08), a Roadmap project addressing the “re-engineering” of the clinical research enterprise. This request is to continue to use the same instrument (the *Core Survey*) to collect information from new and newly identified research networks so that the data in the inventory are current and up-to-date. A new component requests that all networks participating in the inventory annually confirm the accuracy of their information so that the data in the inventory remain valid. The in-depth *Descriptive Survey* component of the previously approved collection is no longer needed, however, as that phase of the project has been completed. Thus, the burden on respondents is significantly reduced.

A.16 Plans for Tabulation and Publication and Project Time Schedule

The *Core Survey* information on characteristics of each clinical research network has been compiled in individual network profiles and is posted on an NIH sponsored web site. The data set contains descriptive information about each of the clinical networks that provided the requested information and agreed to be listed. Only networks giving their approval to have their responses listed for public access are included. No statistical analyses are contemplated for these data. The project time schedule is provided in Table A.16-1.

Table A.16-1 Project time schedule

Activity	Time Schedule
OMB Approval	Before July 31, 2008

Core Survey data collection	Ongoing as needed throughout 2008
Annual Updates data collection #1	January 2009
Core Survey data collection	Ongoing as needed throughout 2009
Annual Updates data collection #2	January 2010
Core Survey data collection	Ongoing as needed throughout 2010
Project termination	February 28, 2010

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed on the data collection documents.

A.18 Exceptions to Certification for Paperwork Reduction Act Submission

This request for review and approval of the collection of information is not requesting any exceptions to the Paperwork Reduction Act.