

# ***NIH Clinical Center***

## ***Request for Generic Clearance for Surveys of Customers and Other Partners from the Office of Management and Budget***

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***The National Institutes of Health Clinical Center,  
Request for Generic Clearance  
for Surveys of Customers and Other Partners  
from the Office of Management and Budget***

The Clinical Center of the National Institutes of Health (Clinical Center) requests that the Office of Management and Budget (OMB) provide the NIH Clinical Center with a continued generic clearance for surveys of our customers and other partners for from October 1, 2007 through September 30, 2009. We have ensured that these survey activities that are designed to gather and measure customers' perceptions of the quality of the Clinical Center's services and operations satisfy the requirements and the spirit of Executive Order (EO) 12862. Clinical Center staff have also reviewed the OMB Manual "Resource Manual for Customer Surveys" and are confident that all our survey activities meet the requirements and follow the guidelines of this manual. Further, the Clinical Center agrees to adhere to the guidelines set forth in both EO 12862 and in the OMB Manual. The Clinical Center recognizes that the generic clearance covers only voluntary surveys of our customers and other partners. Our surveys will be both qualitative and quantitative. Personal identifiers will be excluded from all surveys and additional measures will be taken to ensure the anonymity of respondents. The generic clearance is limited to collection of information from current, past, and potential customers and partners of the Clinical Center.

The Clinical Center's vision is that it will serve as a premier center for clinical research, and as a model of collaborative excellence, the NIH Clinical Center will lead in the design, conduct, training, and impact of clinical research. Input from our customers and partners is an essential component of our efforts to improve our services and operations continuously. Results gathered in these surveys have been, and will continue to be, used to help us improve and refine our goals, to refocus the strategies that we use to address these goals, and to identify areas in which key projects may be designed to improve our services and their outcomes.

Quality management principles have integrated into the Clinical Center's culture. In late 1990, beginning with senior management, all 2000 employees in the Clinical Center were trained in the basic philosophy and tools of "Total Quality Management" (TQM). Within a year a CC vision statement and success statements were crafted and disseminated; an organizational steering committee was created and subsequently reconstituted; the roles of Quality Director and Coordinators were defined and assumed; an annual quality plan was written; departmental guidance teams were formed; a toolmaster network was established; a CORE implementation group was formed for overall coordination of the effort; and a TQM resource center was opened. This initial training was enhanced over the years to include team leader training and was provided quarterly to new employees for several years. Today, Clinical Center employees use the principles and practices of TQM on a daily basis. The process has been institutionalized. To move our quality initiative forward, the Clinical Center needs input from its customers and other partners.

In response to the specific requirements of EO 12862:

- a. Clinical Center leadership has identified and continually refined our major customers and other partners. The 2007 Clinical Center strategic plan identifies the following list of "Stakeholders and Customers":

- Investigators, working both at NIH and extramurally
- Clinical research subjects
- Visitors and families of clinical research subjects
- Referring physicians
- Former physician trainees/employees
- Guest workers/researchers
- Volunteers
- The Department of Health and Human Services
- Congress
- The public
- Regulators, both governmental and industry-based
- Vendors and suppliers

Clinical Center leadership acknowledge that, in the broadest sense, all U.S. citizens and taxpayers are our potential customers.

- b. Historically, the Clinical Center obtained customer input informally from our patients and external customers. Over the past several years, we have had a generic clearance to conduct surveys of our customers and other partners and have used this clearance to improve the care and services provided to our customers. Our planned activities for the next several years reflect our increasing emphasis on performance improvement activities, and our increasing reliance on the valuable data generated from these surveys.
- c. By conducting surveys under the auspices of our previous generic clearance, the Clinical Center established baseline levels of performance, made interventions, and was able to assess the impact of these interventions on our customers' perceptions of quality. Additional surveys will provide baseline levels of satisfaction for previously unsurveyed customers and will provide additional information about the efficacy of ongoing performance improvement activities at the Clinical Center.
- d. The Clinical Center has benchmarked the performance of our organization, as well as that of its individual components, against the performance of organizations that are recognized leaders in the field of clinical research. Customer satisfaction input is an essential component of this benchmarking activity.
- e. The Clinical Center has traditionally sought input from its front-line employees and will continue to do so. Employees' suggestions to improve our services and operations are both welcomed and encouraged; these suggestions are frequently incorporated in our operations. We will continue to seek input from our front-line employees regarding their ideas for improved services for our customers and other partners. In addition, our last employee survey was directly linked (by dimensions of care) to the survey conducted simultaneously of our patients. This approach allows for identification of disconnections between the perceptions of patients and staff and identifies opportunities for performance improvement.

- f. The major mechanisms by which the Clinical Center will request customer input is through surveys and focus groups. The surveys will be tailored specifically to each class of customer and to that class of customer's needs. Surveys will either be collected as written documents, as faxed documents, mailed electronically or collected by telephone from customers.
- g. The field of clinical research has become increasingly complex, challenging, and competitive. The Clinical Center must meet the demands of shifting patient demographics; advancing medical and molecular technologies; dramatic changes in the provision and financing of health care; increasing emphasis on outpatient, rather than inpatient medicine and clinical research; the markedly changing role of academic medical centers; and governmental streamlining initiatives. Competition for patients as subjects in clinical research is intense. Because of the nature of medicine and clinical research, our customer base is both broad and highly diverse. Our initiatives range from pediatrics to geriatrics and involve patients who have acute as well as chronic illnesses. In this increasingly competitive environment, obtaining customer satisfaction information is crucial to the successful achievement or organizational goals.
- h. Information gathered from these surveys of Clinical Center customers and other partners has been, and will continue to be presented to, and used directly by, Clinical Center management and Clinical Center oversight groups to enhance the services and operations of our organization. If the survey process is viewed as encumbering by any of our respondents, Clinical Center management will be made aware of the problem and corrective action will be taken.

In response to the specific requirements of the OMB Manual, “Resource Manual for Customer Surveys”

The Manual delineates twelve steps for designing and conducting surveys of customers and other partners. The Clinical Center agrees to meet each of the steps outlined, to the fullest extent possible.

- a. The Clinical Center will coordinate all survey activity centrally, using the scientific expertise of NIH experts and external expert consultants from the National Research Corporation (NRC+Picker) in survey design, including sample size determination, survey conduct, and statistical interpretation of the data.
- b. The Clinical Center will ensure that problems identified in surveys of customers and other partners will be addressed by Clinical Center leadership. Clinical Center management will integrate the data from these surveys into our continuous improvement strategies. Results from our prior surveys (conducted under our previous generic clearance) have been used successfully for performance improvement activities in the Clinical Center.
- c. Prior to implementing any survey activity covered by this generic clearance, the Clinical Center will provide copies of the survey document, a description of the activity and an estimate of the burden hours involved to OMB.
- d. With respect to review of each proposed survey, NIH has, for over a decade, successfully exercised strong internal control of information collection activities through the OMB chartered “Clinical Exemption Review Committee” and its project clearance staff of two professionals assisted by a coordinator in each of the 26 NIH components.
- e. The Clinical Center agrees to submit annual progress reports, as required in the “Resource Manual for Customer Surveys”. These reports will detail: a summary of the activities undertaken under this generic clearance, a summary of the results obtained from these surveys, the manner in which these data have been used for performance improvement activities, and the efficacy of the interventions. The report will also detail the number of burden hours used in these surveys. Finally, the reports will address any modifications of the clearance agreement that have been identified in the prior year’s activities.

## SUPPORTING STATEMENT FOR REQUEST FOR GENERIC CLEARANCE

### A. JUSTIFICATION

#### 1. Circumstances Making the Collection of Information Necessary

In accordance with Executive Order 12862, the Clinical Center of the National Institutes of Health (Clinical Center) will be conducting frequent surveys of its customers and other partners. These surveys (which will be both quantitative and qualitative) have been, and will be, designed to assess the quality of services we provide to our major internal and external customers. These customers include, but are not limited to, the following groups of individuals: Clinical Center patients, visitors and family members of Clinical Center patients, families of clinical research subjects, referring physicians, former physician trainees/employees, guest workers/researchers, volunteers, referring physicians, vendors, and regulators. As is required by OMB, these surveys will be limited to projects that solicit voluntary opinions and will not collect information that is required or regulated. The Clinical Center had a previous generic clearance and used that clearance to conduct similar surveys. We have used the data generated from these surveys as a fulcrum for our organizational performance improvement activities. We now request ongoing generic approval to conduct satisfaction surveys of our customers and other partners for the next three years.

#### 2. Purpose and Use of the Information

Obtaining information about the satisfaction of customers and other partners is consonant both with EO 12862 as well as good business practices. If the Clinical Center did not collect this information, we would simply not have the knowledge necessary to provide the best services possible to our customers and other partners. The information collected in prior surveys has been used by Clinical Center leadership to identify opportunities for organizational improvement. The initial survey was conducted to provide a baseline and to identify any clear opportunities for improvement. These data have been used successfully to drive performance improvement activities in the Clinical Center in several importance areas of patient care and customer service. These surveys have been, and will continue to be used 1) to assess the quality of care and services provided to the various Clinical Center customers and other partners, 2) to assist with the design of modifications of these services, based on customer input; 3) to develop new services, based on customer need; and 4) to obtain customer feedback about the efficacy of implemented service modifications. Past surveys have led to clear to quality improvement activities that have both enhanced and streamlined Clinical Center operations. The Clinical Center will submit specific survey instruments as they become available and will report the results of completed surveys to DHHS and OMB on a yearly basis. The Clinical Center has attached a projected list of surveys and focus groups that we plan to conduct during the clearance period.

### 3. Use of Information Technology and Burden Reduction

Surveys will be conducted using several methodologies, including e-mail, telephone, direct mail and by conducting focus groups when more detailed information is necessary to design an intervention. The size and scope of the remaining surveys is such as not to warrant investment in computer-assisted telephone interviewing (CATI). The Clinical Center will work with behavioral intramural and extramural scientists and experts in information systems on the to make the surveys the highest quality possible and to assure that these surveys are as non-intrusive as is possible.

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

The National Institutes of Health has an internal review process for surveys that will be used by the Clinical Center to assess the quality of each survey prior to its use. The Clinical Center administration provided direct oversight for any and all surveys conducted under the prior generic clearance and will continue to do so under this one, to avoid duplication of effort and information collected.

### 5. Impact on Small Businesses or Other Small Entities

Small businesses and other small entities may be involved with these surveys; however, the Clinical Center will minimize the burden on these individuals and organizations by seeking satisfaction information on a strictly voluntary basis, and by streamlining these surveys to collect only the minimum amount of information needed to assess the customer's satisfaction with the quality of the services which the Clinical Center provides.

### 6. Consequences of Collecting the Information Less Frequently

To make an adequate evaluation of the service the Clinical Center provides and to design service improvements in a timely manner, the Clinical Center needs to survey the satisfaction of each of its major customer groups at least every other year. To do so less frequently would provide the Clinical Center with inadequate information needed to provide the best services possible to our customers and other partners. Through these surveys, the Clinical Center will evaluate customers' evaluations of the quality and appropriateness of its care and services. In addition, these surveys will assess customers' expectations, desires, and preferences concerning the services that the Clinical Center provides. These data will provide the foundation for new or modified services that can be tailored to meet customer needs and expectations. The net effect of the conduct of these surveys should be improved services provided by the Clinical Center. We are aware of no technical or legal obstacles to reducing this burden.

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

No special circumstances are involved with these surveys. The surveys will be conducted in accordance with the guidelines in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice

The Clinical Center will address comments responding to the Federal Register notices.

The 60-day advanced notice in the Federal Register was published in Vol. 72, page 26,400, on May 9, 2007. One comment regarding resources required to conduct surveys was received during the 60-day comment period.

9. Explanation of any Payment or Gift to respondents

No payments or gifts will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The contractor administering the surveys solely manages survey data collection. The responses to the questionnaire surveys are entirely anonymous to Clinical Center staff and have no identifiers to link them to individual respondents. This confidentiality will be explained to respondents; additionally, respondents will be informed that their responses are voluntary and that no consequences will be associated with not responding. For the electronic surveys, data identifying individual respondents will be separated from the survey responses as they are entered into the data set. This procedure will be explained to respondents, and respondents will be informed that their responses are voluntary and that no consequences will be associated with not responding. Individuals and organizations contacted in the course of these surveys will be assured of the confidentiality of their replies under 42 USC 1306, 20 CFR 401 and 422, 5 USC 552 (Freedom of Information Act) 5 USC 552a (Privacy Act of 1974) and OMB Circular No A-130.

11. Justification for Sensitive Questions

All data collected in these surveys will relate directly to the services provided or planned by the Clinical Center; no sensitive information will be collected.

12. Estimates of Hour Burden, Including Annualized Hourly Costs

The total potential burden on the public (see following tables) is estimated to be 21,884 hours for 58,335 respondents for all surveys that would be conducted under this generic clearance. The annual burden is estimated to be 7,074 hours for 19,305 for 2007, 7,598 hours for 19,205 respondents in 2008, 7,212 hours for 19,825 respondents in 2009.

## FY 2007

CUSTOMER	NUMBER OF RESPONDENTS	FREQUENCY OF RESPONSE	AVERAGE TIME PER RESPONSE	ANNUAL HOUR BURDEN
Clinical Center Patients	5000	1	.5	2500
Family Members of Patients	2000	1	.5	1000
Visitors to the Clinical Center	1000	1	.17	170
Clinical Center Employees	2500	1	.25	625
NIH Investigators	2000	1	.25	625
NIH Intramural Collaborators	2000	1	.17	340
Vendors and Collaborating Commercial Enterprises	2500	1	.33	833
Professionals and Organizations Referring Patients	2000	1	.33	833
Regulators	30	1	.33	10
Volunteers	275	1	.5	138
TOTAL	19,305			7074

## FY 2008

CUSTOMER	NUMBER OF RESPONDENTS	FREQUENCY OF RESPONSE	AVERAGE TIME PER RESPONSE	ANNUAL HOUR BURDEN
Clinical Center Patients	5000	1	.5	2500
Family Members of Patients	3000	1	.5	1500
Visitors to the Clinical Center	1500	1	.17	255
Clinical Center Employees	2500	1	.33	833
NIH Investigators	2400	1	.5	1200
NIH Intramural Collaborators	1500	1	.25	375
Vendors and Collaborating Commercial Enterprises	2000	1	.25	500
Professionals and Organizations Referring Patients	1000	1	.33	333
Regulators	30	1	.33	10
Volunteers	275	1	.33	92
TOTAL	19,205			7598

## FY 2009

CUSTOMER	NUMBER OF RESPONDENTS	FREQUENCY OF RESPONSE	AVERAGE TIME PER RESPONSE	ANNUAL HOUR BURDEN
Clinical Center Patients	5000	1	.5	2500
Family Members of Patients	2000	1	.5	1000
Visitors to the Clinical Center	1000	1	.17	170
Clinical Center Employees	2500	1	.33	833
NIH Investigators	2500	1	.33	833
NIH Intramural Collaborators	1000	1	.17	170
Vendors and Collaborating Commercial Enterprises	2500	1	.25	625
Professionals and Organizations Referring Patients	3000	1	.33	1000
Regulators	25	1	.25	6
Volunteers	300	1	.25	75
TOTAL	19,825			7212

Estimated costs to the respondents consists of their time; time is estimated using a rate of \$10.00 per hour for patients and the public; \$30.00 for vendors, regulators, organizations and \$55.00 for health care professionals. The estimated annual costs to respondents for each year for which the generic clearance is requested is \$159,250 for 2007, \$194,540 for 2008, and \$194,540 for 2009.

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

No additional costs should be incurred by respondents or recordkeepers.

14. Annualized Cost to the Federal Government

The costs to the government include costs associated with: information collection, design, development, document printing, mailing costs, and data entry, management and analysis. Much of the expertise necessary to design, conduct and analyze the results of these surveys is present on the NIH campus. In addition, we have a contract with the NRC+Picker Corporation.

Materials and expertise are readily available both through our external consultants and internally on the NIH campus. Estimated Capital Costs are \$7,000. Estimated Operating and Maintenance costs are \$73,000

15. Explanation for Program Changes or Adjustments

This is an ongoing performance improvement program, designed to gather the perceptions of the quality of care and services provided to the Clinical Center's customers and other partners; these surveys should continue to drive service and program changes, as they have in the past. Such voluntary customer survey work is required by EO 12862.

16. Plans for Tabulation and Publication and Project Time Schedule

As has been the case under the prior generic clearance, results obtained from these surveys will be disseminated to key policy and management officials, CC Oversight Committees, NIH management, Clinical Center management, NIH investigators, Clinical Center employees and to the public within six months of the survey's completion and will be used to drive the organization's performance improvement activities.

17. Reports Clearance Expiration Date

The reports clearance expiration date should be printed on each of these surveys, since these will be one-time surveys, designed to assess the prior year's services.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

The Clinical Center is not requesting an exception to the certification requirements.

