Mini Supporting Statement
For Expedited Review of the
National Institutes of Health Clinical Center
Survey of Patients' Perceptions of the Impact
of Third Party Billing on Clinical Research Participation
(Part of Generic Clearance, OMB Control Number: 0925-0458)

Section A

A.1 Circumstances Requiring the Collection of Data

In general, National Institutes of Health Clinical Center survey activities under this generic clearance are designed to gather and measure customers' and other partners' perceptions of the quality of the Clinical Center's services and operations. This focused sub-survey of Clinical Center patients will be conducted over an approximately 5 month period of time and will help fulfill the requirements of:

- Executive Order 12862, "Setting Customer Service Standards," which directs Agencies to continually reform their management practices and operations to provide service to the public that matches or exceeds the best service available in the private sector; and
- The March 3, 1998 White House Memorandum, "Conducting Conversations with America to Further Improve Customer Service," which directs Agencies to determine the kind and quality of service its customers want as well as their level of satisfaction with existing services.

A.2 Purposes and Uses of the Data

The purpose of this survey is to collect information about National Institutes of Health Clinical Center's patients' perceptions about the impact that billing patients' insurance companies for routine/standard care would have on the patients' likelihood to participate in clinical research protocols at the Clinical Center. This information will be used to guide program design and management.

A.3 Use of Information Technology to Reduce Burden

The size and scope of this sub-survey (1-4 questions) does not warrant investment in computer-assisted telephone interviewing (CATI) or other technology.

A.4 Efforts to Identify Duplication

Users will be asked to complete the survey only once.

A.5. Small Business

N/A

A.6 Consequences of Not Collecting the Information

Absent this survey, the CC would not have a mechanism for determining patients' perceptions of their likelihood to participate in clinical research protocols at the Clinical Center upon the implementation of third party recovery for routine/standard care.

A7. Special Circumstances Justifying Inconsistencies with Guidelines in 5 C.F.R. 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.

A.8. Consultation Outside the Agency

N/A

A.9. Payments or Gifts to Respondents

No payment or gift will be provided to respondents.

A.10. Assurance of Confidentiality

The contractor administering the surveys solely manages survey data collection. The responses to the surveys are entirely anonymous to Clinical Center staff and have no identifiers to link them to individual respondents. This anonymity 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. Data identifying individual respondents will be separated from the survey responses as they are entered into the data set. Individuals and organizations contacted in the course of these surveys will be assured of the confidentiality of their replies as permitted by law 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.

A.11 Questions of a Sensitive Nature

No questions will be asked of a personal or sensitive nature.

A.12Estimates of Response of Burden

Estimates of Annual Hours Burden				
Types of Respondents	Number of Respondents	Frequency of Response	Average Response Time	Annual Hour Burden
Patients (800 pts x 5 months)	4000	1	15/60	1000 hrs (60K min)

A.13. Estimate of Total Capital and Startup Costs/Operation and Maintenance Costs to Respondents or Record Keepers

N/A

A.14. Estimates of Costs to the Federal Government

The estimated annual cost to the Federal government is $7,000.

A.15. Changes in Burden
N/A

A.16. Plans for Publication, Analysis and Schedule
As has been the case under the prior generic clearance, results obtained from this sub-survey will be disseminated to key policy and management officials at the survey's completion and will be used to drive the organization's performance improvement activities.

A.17. Approval to Not Display Expiration Date
We are not requesting an exemption to the display of the OMB Expiration date.

A.18 Exceptions to Item 19 of OMB form 83-I
These surveys will comply with the requirements in 5 CFR 1320.9.

Section B

B.1. Respondent Universe and Sampling Methods
The survey was created to obtain information from current (not prospective) patients of the NIH Clinical Center. It will be used to assist in the measurement of patients' perceptions of their likelihood to continue to participate in clinical research protocols at the Clinical Center upon the implementation of billing patients' insurance companies for routine/standard care.

B.2. Information Collection Procedures/Limitations of the Study
The Clinical Center will collect all information in a manner that is consistent with the following principles:

- Appropriate sample sizes will be determined for the survey so that the burden is minimized while reliable estimates are produced.

- Participation will be fully voluntary, and non participation will have no impact on eligibility for participation in clinical research.

- Collected information will be limited to that which is needed to assess patients' perceptions.

B.3. Methods for Maximizing the Response Rate and Addressing Issues of Nonresponse
Consistent with sound survey methodology, the design of the survey will include approaches to maximize response rates, while retaining the voluntary nature of the effort.

B.4. Tests of Procedures of Methods
All pre-testings will be carried out at a level and in a manner consistent with the specific survey.