

Supporting Statement A For:

Multidisciplinary Treatment Planning (MTP) within the
National Cancer Institute (NCI) Community Cancer Centers Program

March 28, 2014

Irene Prabhu Das
Division of Cancer Control & Population Sciences
Applied Research Program, Outcomes Research Branch
National Cancer Institute

9609 Medical Center Drive
Room 3E-518 MSC 9704
Bethesda, MD 20892-0704
Telephone: 240-276-6799
Fax: 240-276-7906
E-mail: prabhudasi@mail.nih.gov

Table of Contents

A. Justification.....0

A.1 CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY.....0

A.2. PURPOSE AND USE OF THE INFORMATION COLLECTION.....2

A.3 USE OF IMPROVED INFORMATION TECHNOLOGY AND BURDEN REDUCTION.....4

A.4 EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION.....5

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES.....6

A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY.....6

A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5.....6

A.8 COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT
OUTSIDE THE AGENCY.....6

A.9 EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS.....7

A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS.....7

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS.....8

A.12 ESTIMATES OF ANNUALIZED BURDEN HOURS AND COSTS.....9

A.13 ESTIMATES OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS AND
RECORD KEEPERS.....10

A.14 ANNUALIZED COST TO THE FEDERAL GOVERNMENT.....10

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS.....12

A.16 PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE.....12

A.17 REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE.....13

A.18 EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS.....14

LIST OF ATTACHMENTS

Attachment 1: Background Information & References/Citations

Attachment 2: Consent, Screenshots and PDF¹ of the Surveys

2Ai: Head and Neck Survey Screenshots

2Aii: Head and Neck Survey PDF Sent with Introduction

2Bi: Breast Survey Screenshots

2Bii: Breast Survey PDF Sent with Introduction

2Ci: Lung Survey Screenshots 2Cii: Lung Survey PDF Sent with Introduction

Attachment 3: Tumor Site Assignment

Attachment 4: Introduction and Reminder Emails

Attachment 5: List of Consultants

Attachment 6: Privacy Act Memo

Attachment 7: OHSR Approval Letter

Attachment 8: Telephone Reminder Script

This is a request for OMB to approve the new submission titled, “Multidisciplinary Treatment Planning (MTP) within the NCI Community Cancer Centers Program (NCCCP)” for one year. The aim of this data collection is to characterize how NCCCP hospitals define, structure, and implement multidisciplinary treatment planning (MTP), which initiates a coordinated approach to multidisciplinary care. The web-based, organizational survey will gather data on NCCCP hospitals’ definitions and terms for multidisciplinary treatment planning, composition of provider teams, meeting procedures, and patient involvement in the process. Information collected from NCCCP hospitals will add to the knowledge being generated and provide the foundation for future research

¹ PDF of the survey will be sent in advance, along with the email invitation so that the hospital staff can review and collaborate on responding to the questions. The screenshots are also supplied to demonstrate what the hospital staff will see when they enter their responses on-line.

on multidisciplinary care approaches in cancer. A total of 21 hospitals participating in the NCCCP through June 2014 will be requested to complete the survey.

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Public Health Service Act, Section 412 (42 USC § 285a-1) and Section 413 (42 USC § 285a-2) authorizes the National Cancer Institute (NCI) to establish and support programs for the detection, diagnosis, prevention and treatment of cancer; and to collect, identify, analyze and disseminate information on cancer research, diagnosis, prevention, and treatment.

The Outcomes Research Branch (ORB) within the Division of Cancer Control and Population Sciences seeks to coordinate and sponsor research that measures, evaluates, and improves patient-centered outcomes of cancer care delivery across the cancer care continuum. Pursuant to this mission, ORB supports applied research that assesses and enhances the quality of cancer care at all levels that include the health care organization, health care system, providers, and patients. Establishing an understanding of multidisciplinary care organization and characterizing the diverse ways this approach is conceptualized and implemented is one way of identifying key research priorities to assess and enhance quality cancer care.

The proposed data collection among the NCI Community Cancer Centers Program (NCCCP) is exploratory and is intended to understand how multidisciplinary treatment planning, a fundamental element of multidisciplinary care, is organized and implemented. The process of coordination, convening, and communicating among clinicians from different disciplines in order to create plans for cancer treatment is not well understood.² While multidisciplinary care and treatment planning processes are promoted at hospitals, no consistent methods and established

² Fennell, Prabhu Das, Clauser, Petrelli, Salner. (2010). The organization of multidisciplinary care teams: Modeling internal and external influences on cancer care quality.

² Haward R, Amiz Z, Borill C, et al. Breast cancer teams: the impact of constitution, new cancer workload, and methods of operation on effectiveness. *Br J Cancer*. 2008;85:15–22.

metrics exist to determine how this approach to engage various clinicians and care providers improves the delivery of quality cancer care and improves patient outcomes.²

The NCI Community Cancer Centers Program (NCCCP) currently funds 21 hospitals to deliver enhanced quality care and support clinical, basic, and population-based research (<http://ncccp.cancer.gov/about/index.htm>). Program goals are directed toward reducing cancer care disparities, increasing accrual to clinical trials, improving quality of care provided at community hospitals, enhancing survivorship and palliative care services, and expanding the use of electronic medical records to facilitate data sharing. A priority within the Quality of Care component of the NCCCP has been to develop and maintain multidisciplinary care programs for specific tumor types to promote prospective treatment planning. Multidisciplinary care engages the various clinicians and other care providers involved in the care of the patient to review the available evidence, discuss the appropriate treatment for the patient prospectively, and coordinate the overall treatment and care in the patients' best interest for improved outcomes. While multidisciplinary care programs in cancer are growing rapidly and are being promoted in many hospitals, the first step, multidisciplinary treatment planning, is not well understood, and has not been described in the limited literature available in this arena (**Attachment 1**).

The NCI has an ongoing interest in developing research and improving care delivery in the community setting and recently approved the NCI Community Oncology Research Program (NCORP), in which a research focus area is Cancer Care Delivery Research (CCDR). This field of research studies how social factors, financing systems, organizational structures and processes, health technologies, and healthcare provider and patient behaviors affect access to cancer care, the quality and cost of cancer care, and ultimately the health and well-being of cancer patients and survivors. Individuals, families, organizations, institutions, providers,

communities, populations, and their interactions are all incorporated within CCDR. Findings may inform future research questions essential to understanding the different models of multidisciplinary treatment planning that are practiced and how they may contribute to assessing the quality of care patients receive. This research could also help inform the NCORP research bases and other NCI-sponsored initiatives (e.g. Cancer Research Network) and be used in the development of study questions that may include the following, not in any particular order:

- *What factors facilitate or hinder the development of multidisciplinary treatment planning teams?*
- *How does a coordinated strategy like MTP enhance the quality of cancer care delivery?*
- *What are the expectations and perceptions of primary care physician engagement in MTP by oncology specialists and primary care physicians?*
- *What are the measures of MTP effectiveness at the organizational & physician levels?*

A.2 Purpose and Use of the Information

The purpose for this survey is to characterize multidisciplinary treatment planning in NCCCP hospitals. The unique aspect of the NCCCP is that it has an explicit program goal to enhance multidisciplinary care. Currently, NCCCP hospitals are establishing new or expanding existing multidisciplinary care for a particular cancer type they have selected and reporting actions taken to support this endeavor. The findings from the MTP survey of the 21 NCCCP hospitals will describe how multidisciplinary treatment planning is structured and the different ways in which it is being implemented in the community setting, providing insight into the context of developing and implementing multidisciplinary care.

The NCCCP sites will complete the survey online and data submitted will be reviewed by the NCI/NIH investigators. Once the data are analyzed, the data will be shared with the NCCCP sites, community oncologists, and other cancer care specialists as well as health services researchers around the country. The results from this exploratory study of this select network of

hospitals will inform future research questions that are essential to understanding the different models of multidisciplinary treatment planning that are practiced and that may contribute to assessing the quality of care patients receive.

The proposed MTP survey will obtain facility level data and not individual clinician data. The questions in the survey are designed to capture data on MTP for a specific tumor site. Questions are presented in seven sections and include a few skip patterns. A total of 69 items are on the survey: 64 items are closed-ended and five items are open-ended (**Attachment 2**). Each NCCCP hospital has been assigned one of three selected tumor sites, and respondents will be requested to complete the survey questions on multidisciplinary care for their assigned tumor site (**Attachment 3**). This survey is intended to reflect the organization's understanding and operations of multidisciplinary treatment planning (MTP) and not an individual perspective. Hence, participants are encouraged to consult with as many NCCCP colleagues at their facility as well as other hospital staff not engaged in the NCCCP at their facilities to improve the accuracy of their responses.

The following research questions will be examined:

1. How do NCCCP hospitals define MTP?
2. How do the MTP team structures differ across the NCCCP?
3. How do MTP team processes vary across the NCCCP?

There will be three identical surveys for each tumor site. Respondents will be asked to respond to the following:

- alignment with study definition and terminology used for multidisciplinary treatment planning;
- frequency of MTP meetings;
- patient involvement in MTP meetings (e.g., invitation to attend MTP meetings, communication pertinent to MTP meetings);

- structure and organization of MTP teams to include composition, designated roles, and attendance; mode of conducting MTP meetings;
- evaluation of clinical trial availability and eligibility during MTP meetings; post-meeting follow-up; development and distribution of treatment plans and summaries; medical record infrastructure supporting MTP;
- compensation and incentives for MTP participation;
- evaluation of MTP meetings.

In addition, there are three questions pertaining to the organization's policies, procedures, guidelines and evaluation documents (**Attachment 2**: # 9, 17, & 62). If the NCCCP hospitals agree to share them, a member of the NCI/NIH research team will follow-up with them via e-mail to obtain the documents (**Attachment 4**). These documents will be examined using qualitative content analysis to supplement MTP characterization at NCCCP hospitals.

A.3 Use of Improved Information Technology and Burden Reduction

The NCCCP sites will complete the survey online via the internet using Survey Monkey (www.surveymonkey.com). This mode of data collection was chosen as it is low-cost and efficient for respondents to use, and because all respondents will have ready access to e-mail and the internet. Respondents can save completed information and return to continue the survey after consulting with other staff at their facility, if necessary.

The NCI Privacy Act Coordinator was consulted on July 31, 2013 and determined that a Privacy Impact Assessment (PIA) was not necessary because there is no personally identifiable information being collected and stored in a record system designed to be retrieved by the name of an individual, or identifier linked to them.

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

In 2012, the American College of Surgeons Commission on Cancer (CoC) administered a *similar* questionnaire to the one currently proposed to CoC-accredited facilities, in order to understand how multidisciplinary treatment planning is implemented. However, the CoC survey did not include NCCCP sites because clinicians participating in the NCCCP provided expert review early in the survey development process, and were on that basis considered ineligible for that survey. The NCI provided the technical expertise to develop the survey and conducted the cognitive testing for their instrument (Attachment 4: 0925-0589-07; Approved January 13, 2011).

The proposed survey is also different from the CoC in three ways: purpose, approach, and questions administered. The fundamental purpose of the NCCCP MTP survey is to contribute toward a more comprehensive understanding of MTP implemented within a program context that has had specific emphases on establishing and enhancing multidisciplinary care program development. The tumor sites for which MTP data will be collected were purposively selected for NCCCP hospitals based on their previous MTP activities for certain tumor sites and their choice of tumor type to develop. Finally, several questions and response options for the NCCCP have been modified to be more clear and relevant to NCCCP activities. Several discussions have been held among the NCI/NIH research team and consultants pertaining to response options, clarity of certain questions, as well as addition of a few questions. The NCCCP MTP survey instrument has been adapted from the CoC survey, based on the preliminary analyses of the CoC survey. The results revealed that the questions may not have been clear or the responses were not directly applicable. While some of the original questions and options may have been retained, the NCCCP MTP instrument does not duplicate the CoC-survey instrument.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A.6 Consequences of Collecting the Information Less Frequently

This is a one-time data collection.

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

The proposed survey is a one-time, exploratory study designed to understand multidisciplinary treatment planning within the NCCCP hospitals. Findings from this survey are intended to inform research in multidisciplinary care in cancer. This study is not designed to generalize results beyond the NCCCP sites to be surveyed. This is the only special circumstance relating to the guideline of 5 CFR 1320.5.

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

The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on November 1, 2013, Vol. 78, P. 65675. No public comments were received.

The NCCCP has had a program emphasis on developing multidisciplinary care programs and improving the process of prospective treatment planning. Accordingly, members of the NCCCP Program Advisory Committee (NPAC), and the Director and Associate Director for the NCCCP were consulted to provide their comments and perspectives relevant to this one-time

data collection, clarity of instructions, data items to be collected, analyzed, and reported (**Attachment 5**). Additionally, two senior researchers within the Applied Research Program were also consulted regarding survey items (**Attachment 5**). Materials reviewed include the actual survey instrument (**Attachment 2**), cover e-mail, and the reminder e-mails (**Attachment 4**). Several consultants provided expert review on the survey instrument and revisions to the original CoC survey items, as well as the overall project at various points during the planning process (**Attachment 5**).

A.9 Explanation of Any Payment or Gift to Respondents

No monetary incentives will be provided to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

Unique identifiers for each participating hospital will be assigned by NCI/NIH investigators and noted on the survey. No hospital names and/or physicians' names will be on the survey instrument. Only the NCI/NIH investigators will have access to the key linking the unique identifiers and the participating hospitals. Data at the organizational level will be collected and no personally identifiable information (PII) at the physician or staff member level will be collected.

In addition, the web link to the online survey as well as a PDF copy of a blank survey instrument sent to the NCCCP Principal Investigator and to the NCCCP Quality of Care component lead will be using NIH's Secure Email and File Transfer Service secured by a Verisign 128 bit encryption. This service allows NIH users and its customers to send email securely and confidentially over an SSL/encrypted connection, with or without large documents.

Furthermore, Secure Sockets Layer, a protocol initially developed for transmitting private documents or information via the Internet, will be employed as part of the survey data collection using Survey Monkey. All data submitted will be housed on the password-protected account of the Principal Investigator on the Survey Monkey website. Security protocols will be implemented to ensure that all data are recorded and stored in such a manner that individual research subjects cannot be identified directly or through identifiers. Data sets created will contain no means of identifying individual NCCCP hospitals. Electronic data will be password protected and stored by the research team and will be destroyed after a year. All results will be reported in aggregate to protect the confidentiality of the participants.

The NIH Privacy Officer has reviewed the information collection and has determined that no personally identifiable information is being collected, thus, the Privacy Act does not apply (**Attachment 6**).

This study has been reviewed by the Office of Human Subjects Research and determined to be “Exempt” (**Attachment7**).

A.11 Justification for Sensitive Questions

Only data at the organizational level will be obtained in the proposed data collection. No PII and race/ethnicity data will be collected. No sensitive questions are included in the survey.

A.12 Estimates of Annualized Burden Hours and Costs

Hospital-level staff and clinicians involved in the NCCCP at the 21 hospitals will be approached to complete the MTP survey voluntarily. Information will be collected over an 8-week period between March and May, 2014. The survey is expected to take no more than one

hour to complete. After two e-mail reminders, the non-responders will receive a telephone call confirming that they received the email invitation to complete the survey. Those who have not received the email will be asked to confirm their email address (**Attachment 8**). The annualized estimate of respondent burden is a total of 22 hours (Table A.12-1).

Table A.12-1 Estimates of Hour Burden for NCCCP MTP Survey

Form Name	Types of Respondents	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Survey (Attach 2)	Private Sector: Not for Profit NCI	21	1	1	21
Telephone Reminder (Attach 8)	Community Cancer Center Program Hospitals	21	1	2/60	1
Total					22

The cost burden is essentially the time required to read the instructions, the consent form, and complete the survey, if necessary, with consultation from colleagues. The mean hourly wage rate is \$88.86 for Physicians and Surgeons, as indicated by the May 2012 National Occupational Employment and Wage Estimates, United States (http://www.bls.gov/oes/current/oes_nat.htm#29-0000). The cost to the respondents for the total burden is estimated to be \$1,928.26 (Table A.12-2); this is both the annualized cost and the cost over the period of the entire information collection.

Table A.12-2 Annualized Cost to Respondents for NCCCP MTP Survey

Types of Respondents	Number of Respondents	Frequency of Response	Average Time per Response (in hours)	Hourly Wage Rate	Total Respondent Cost
Private Sector: Not for Profit NCI Community	21	1	1	\$88.86	\$1,866.06

Cancer Center Program Hospitals	21	1	2/60	\$88.86	\$62.21
Total					\$1,928.26

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no direct costs to respondents other than those presented in section A.12.

A.14 Annualized Cost to the Federal Government

NCI costs are based primarily on labor (Federal employees, \$7,846; and contractors, \$4,263.03) with the exception of the software license purchase for Survey Monkey (\$280). These costs contribute to an annual (and total) cost of \$12,389 to the Federal government (See Table A.14-1).

Costs have been calculated to manage and support tasks for the MTP survey, from survey administration through presentation of findings to NCCCP. This revision also includes the pre-OMB approval costs which, for the most part, were not included in the original calculations. Federal Government staff is required to conduct research and development, PRA/OMB Clearance development, and to lead and support this study. The Health Scientist, Nurse Consultant and a Research Assistant will be responsible for the project management, planning, and oversight for the study.

Additionally, contractors that will be employed include a survey statistician and staff to provide biomedical computing support. Specifically, the contract tasks will include performing the planned analyses, creation and printing of tables and charts for the presentation to the NCCCP hospitals, development of summary reports, and participation in conference calls with the project team.

Table A.14-1 Cost to Federal Government

Tasks/Personnel	Annual Salary	% of Time	Cost
PRE OMB Approval Costs			
Government Personnel Costs:			
Health Scientist/PI – GS13 ³ , Step 5	\$100,904	2%	\$2,018.08
Nurse Consultant/Co-PI ⁴ – GS14, Step 1	\$105,211	1%	\$1,052.11
Research Assistant – GS10, Step 1	\$56,857	2%	\$1,137.14
Non-Personnel Costs:			
Survey Monkey License	NA	NA	\$280
POST OMB Approval Costs			
Government Personnel Costs:			
Health Scientist/PI – GS13, Step 5	\$100,904	2%	\$2,018.08
Nurse Consultant/Co-PI – GS14, Step 1	\$105,211	1%	\$1,052.11
Research Assistant – GS10, Step 1	\$56,857	1%	\$568.57
Contractor Personnel Costs:			
Survey Statistician – equiv. GS14	\$105,211	¼ %	\$263.03
Analysis and Dissemination (for analytic support via biomedical computing support contract)			\$4,000.00
Grand Total			\$12,389.12

A.15 Explanation for Program Changes or Adjustments

This is new information collection.

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

The objective of this cross-sectional survey is to understand how multidisciplinary treatment planning (MTP) is organized and implemented at NCCCP hospitals. The analysis of the survey results, therefore, will be descriptive to characterize MTP within the NCCCP context.

³ Based on 2013 OPM Pay Schedule for Washington/DC area: <http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2013/general-schedule/>

⁴ The annual salary of the Nurse Consultant is higher than the Health Scientist because the former has been employed by the Federal Government for a longer period of time.

A.16-1: Analysis of the MTP Survey Data

Preliminary analysis will involve merging hospital characteristics with the survey responses into the final analytic dataset. These demographic characteristics include CoC cancer program category, assigned tumor type, number of hospital beds, and annual cancer case volume. Once the data are collected, standard data quality checks will be conducted for accuracy and completeness. A non-response adjustment will be conducted if the response rate is less than 100%. Subsequently, univariate analyses will be conducted to examine variations in response by survey question (e.g., range, means, mode standard deviation, variance, etc.). Additionally, simple relationships between hospital characteristics and dimensions of MTP team structure, process, and evaluation will be examined. Another set of descriptive analyses will examine whether requests for MTP-related documents were successful: (1) How many requested documents were actually submitted and by what types of cancer programs? (2) What major patterns are evident in document format and content? Qualitative content and thematic analysis will be conducted for the submitted hospital documents. All data will be analyzed by the NCI/NIH research team.

A.16-2: Project Time Schedule

NCCCP hospitals will receive notification via e-mail within one week of OMB approval. Following this notification, the NCI/NIH research team will initiate contact to begin fielding the survey within two weeks of receiving OMB approval. The timeline for data collection and analyses is presented below in Table A.16-1.

A.16 – 1 Project Time Schedule After OMB Approval

Activity	Schedule (Weeks after OMB approval)
----------	--

E-mail contact with NCCCP PI and QoC Lead	Weeks 1 - 2
Administer online MTP survey	Weeks 1 through 8
Send 1 st reminder for non-respondents	Week 4
Send 2 nd reminder for non-respondents	Week 6
Telephone reminder of non-respondents	Week 7
Complete survey data collection	Week 8
Analyses	Weeks 9 - 20 (3 months)
Share findings with NCCCP (to be scheduled as webinar)	Weeks 15 – 19 (1 month)

Findings from the analyses will be disseminated through multiple channels, including a webinar with the NCCCP hospitals, a summary report in electronic format posted on the Applied Research Program website: <http://appliedresearch.cancer.gov/>, and the NCCCP website: <http://ncccp.cancer.gov/> for survey participants. In addition, the NCI/NIH research team will submit presentations for national conferences and submit a paper to a peer-reviewed journal.

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

The survey instrument and the online version of the survey will prominently display the OMB approval number and expiration date in the upper right hand corner, close to the control number.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

The NCCCP MTP survey data collection does not require any exceptions to the Certificate for Paperwork Reduction Act (5 CFR 1320.9).