DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: November 29, 2010

To: Office of Management and Budget (OMB)

Through: Seleda Perryman, DHHS Report Clearance Officer
Mikia Currie, Program Analyst, NIH Project Clearance Branch, OPERA
Vivian Horovitch-Kelley, NCI OMB Project Clearance Liaison, OMAA

From: Irene Prabhu Das, Project Officer
Division of Cancer Control and Population Sciences (DCCPS),
National Cancer Institute/NIH

Subject: Cognitive Testing for Multidisciplinary Care Survey
Generic Sub-study under **"Questionnaire Cognitive Interviewing and Pretesting," OMB No. 0925-0589-07, Expiration Date 5/31/2011**

Background, Need and Use of Information

With the growth of multi-modality cancer therapies, cancer specialists (surgeons, radiation oncologists and medical oncologists) need to communicate and coordinate treatment planning among themselves and with cancer patients more than ever. As a result, community cancer centers have been developing a wide variety of multidisciplinary care programs to facilitate improved coordinated cancer care and execution. Little is known about the variation in program structures, organizational processes and methods of engaging patients in these multidisciplinary care programs. A targeted review of the literature was conducted to examine the organization and the operation of the Multidisciplinary Care (MDC) team structure[1] and found the literature scant regarding description of various models and how they varied by environmental context and characteristics of the clinical specialties represented on the MDC teams as well as their impact on the quality of care provided to the patient.

Since there has been very little systematic examination of how multidisciplinary care works in a cancer setting this study will explore using a survey to expand existing knowledge of multidisciplinary care. The NCI's Division of Cancer Control and Population Sciences research

1 Fennell ML, Prabhu Das I, Clauser SB, Petrelli N, and Salner A (2010). The Organization of Multidisciplinary Care Teams: Modeling Internal and External Influences on Cancer Care Quality. J Natl Cancer Inst Monogr;40:72–80.

team is collaborating with the American College of Surgeons, Commission on Cancer (CoC) to develop and cognitively test questions on the Multidisciplinary Care (MDC) survey with the support of the contractor, Westat. Findings from the cognitive interviews will be used to improve any problems with questions prior to finalizing the MDC Survey for administration by the Commission on Cancer.

Respondents, Methodology, and Research Instrument

Respondents for the cognitive interviews will be physicians and administrators, mostly in hospital settings. NCI and CoC will provide Westat with a list of names of physicians or administrators who are eligible and interested in participating in cognitive testing. Interested individuals will be contacted by Westat to be scheduled at a time and place most convenient for the respondents who agree to participate **(Attachment 7A)**.

As many interviews as possible will be conducted face-to-face. However, it is anticipated a significant number of respondents who have been identified will be non-local to the metropolitan DC area. Telephone interviews will be conducted with all non-local respondents as well as with local respondents who express a preference for participating in the interview over the telephone.

Prior to conducting the interview, an interview packet will be mailed to each participant. The packet for respondents to be interviewed in person will contain a cover letter **(Attachment 7B)** with instructions, and a blank survey **(Attachment 7C)** that they will need to complete before the interview. The packet for respondents to be interviewed by telephone will contain a cover letter **(Attachment 7B)** with instructions, a blank survey **(Attachment 7C)** that they will need to complete before the interview, a consent form **(Attachment 7D)**, and a return mail envelope. Non-local respondents have a choice of returning the completed survey by fax, email, or mail, in an envelope addressed to Westat and with a Westat return address. The survey module will be marked with respondents' IDs before they are mailed out so that the researchers know where each survey is coming from when they are returned.

The cognitive interviews will be conducted in two phases: an initial phase (Phase 1) during which the survey will be tested, and a second phase (Phase 2) for those questions requiring additional revisions based on Phase 1 comments. Phase 2 interviews will focus only on the questions that were revised based on Phase 1 interviews.

The interviews will take approximately one hour to complete. In recent surveys sponsored by the National Cancer Institute such as the:

- NCI Cancer.gov Evolution – User Focus Groups and Triads (OMB no. 0925-0046-02) $150 for physicians to participate in focus groups;
- Primary Care Physician Cancer Screening Survey, National Survey of Energy Balance-related Care among Primary Care Physicians (OMB No. 0925-0583) $60 was given for 2 surveys, each 30 minutes long;
- Survey of Physician Attitudes Regarding the Care of Cancer Survivors (SPARCCS) (OMB No. 0925-0595) $50 was given for completion of a 20 minute survey, and

In addition, cognitive interviews for other studies have provided higher amounts for incentives for physician participation:

- Cancer Care Outcomes Research & Surveillance Consortium (CanCORS), a collaboration between NCI and the Department of Veteran Affairs provided $150
- Community Tracking Study's (CTS) Physician Survey sponsored by the Center for Studying Health System Change (HSC) provided $100

For this study, the oncologists are asked to complete a 30 minute survey, as well as a one hour cognitive interview. Thus, given the previous incentives, a stipend of $150 will be given to the respondents as an appreciation of their time and participation in the survey and cognitive interviews. The method of payment will be by check, which will be mailed after the interview is over. Participants will get the full stipend even if they terminate the interview at any point.

At the start of each telephone interview, interviewers will refer the respondent to the consent form **(Attachment 7D)** and summarize its key points. At the start of the face-to-face cognitive interview, the respondent will be provided with a hard copy of the form and information on the informed consent will be reinforced through a verbal explanation. The informed consent includes a description of the study, potential risks of participating, the right to terminate participation at any point in time, steps taken to protect anonymity, and how the interview information will be handled and used by the study. Participants will be asked for their permission to audiotape the interview. It will also be stressed that study staff will secure participants' information and that no names will be recorded on surveys or during the audio taping. Participants will be reminded that they have the right to not answer any questions they are uncomfortable with or terminate their participation at any point in the interview. Any questions participants may have about study procedures or their rights as a participant will be answered at this time. Contact information is provided on the form should participants have any questions about the study or their rights at any point during the study.

All cognitive interviews will be conducted by experienced survey methodologists. The cognitive probes will focus primarily on item interpretation and ease of response. Interviewers will also ask a set of probes to get at respondents' overall impressions of the instrument, as well as suggestions for improvement, such as rewording or changing the order in which questions are presented. Additional issues to be discussed may include: general willingness to participate, potential motivators for participating, and any issues seen as relevant from the multidisciplinary care provider's perspective. A moderator's guide is **Attachment 7E**.

The interview results will be analyzed in a series of steps. The first step is for each interviewer to review and synthesize the data (from the audio-recordings and from any notes she may have taken) from her own interviews. During this step, the interviewer identifies themes within each respondent's interview and across all the interviews she conducted. The themes are organized by individual survey items and for respondents' overall reactions to the survey. In the second step, all interviewers meet and discuss themes they have identified. As a group and with the guidance of the lead analyst, the team identifies common themes (as well as unique situations worthy of notice) within and across all interviews. The team also begins to identify recommendations for revising the survey based on the cognitive interview results. In the final step, the lead analyst

conducts a final review of all interview data and organizes the themes into a document which describes the findings and recommendations. This final review of the data ensures that the recommendations are thoroughly grounded in the cognitive interview data.

Other Considerations

This research presents no more than minimal risk of harm to subjects and involves no procedures for which consent is normally required outside the research context, and thus a waiver of written documentation of informed consent in accordance with CFR 46.117 (c) (2) has been requested for this effort through the NIH Office of Human Subjects Research (OHSR). Additionally, Westat IRB has reviewed and approved this research **(Attachment 7F)**

All participant responses will be captured on audiotape and through the interviewers' handwritten notes. Names will not be included on the survey, interviewer notes, or the audio recording.

The survey does not collect sensitive personal information. Risks to participants are low. Since no personal identifiers will be collected for the survey and names will not be included or mentioned in audio-taping, there is minimal risk that participant anonymity will be lost. There are no direct benefits to participants. Indirect benefits include helping to improve the survey and, ultimately, increasing healthcare professionals' knowledge about multidisciplinary care in a cancer setting.

Access to data will be limited to those authorized to work on the project. Names will not be included on the survey, interviewer notes, or any audio recording. In the results report, interview data will be presented in aggregate form only and any quotes used will not be attributed by name. Westat facilities have 24 hour security, and any identifiable data will be either stored on secure servers accessible only with passwords, or stored in locked rooms or cabinets.

The following documents will hold participant's contact information:

- Scheduling Script (name/address/phone number);
- Envelope containing a survey that will be mailed to respondents prior to the cognitive interview (name/address);
- Cover letter with instructions for filling out and returning the survey (name/address);
- Incentive check (name/address)

These materials will be kept separate from other documents that will hold respondent data (completed survey modules; protocols with interviewer notes on them; audiofiles). The audiofiles will not contain any identifying information. Hard copy documents with respondent data will show an ID only. The project will also use an Excel spreadsheet to show the dates and times of each interview, along with key demographic data for each respondent. This spreadsheet will contain both respondent ID and first name only. All other respondent contact information (full name/address/phone number) will not be stored electronically. Respondent contact information will remain de-linked from respondent data throughout the life of the project. All hard copy documents (completed scheduling scripts and signed consent forms) will be maintained in locked file cabinets separate from the completed surveys and interview protocols.

The Excel tracking spreadsheet and audiofiles will be maintained seperately on a password-protected site. The hard copy documents (with exception of the consent forms), Excel spreadsheet and audio files will be destroyed within 3 months after the end of the contract period.

It is anticipated that the completion of the blank survey and the cognitive interview will take approximately 90 minutes to complete. The total respondent burden for this effort is 26 hours. This effort will account for less than 2 percent of the total burden hours (1800) granted in OMB No. 0925-0589 approved package.

Estimates of Hour Burden					
Types of Respondents	Instrument	Number of Respondents	Frequency of Response	Average Time Per Response	Total Hour Burden
Physicians and Administrators	Scheduling Script (Attachment 7A)	18	1	10/60 (0.17)	3
	Blank Survey and Cognitive Interview (Attachments 7C and 7D)	18	1	90/60 (1.5 hours)	27
TOTALS		36			30

List of Attachments (Attached Below)
Attachment 7B: Cover Letter
Attachment 7D: Consent Form
Attachment 7F: Westat IRB Approval

List of Attachments (Attached in a Separate File)
Attachment 7A: Scheduling Script
Attachment 7C: MDC Team Structure "Blank" Survey
Attachment 7E: Moderator's Guide

Attachment 7B: Cover Letter

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RESEARCH CORPORATION

1650 Research Boulevard • Rockville, Maryland 20850-3195
tel. 301-251-1500 • fax 301-294-2040 • www.westat.com

2/2/2021

Mr. / Ms. / Dr. XXX
Address
City, State ZIP

Mr. / Ms. / Dr. XXX:

Thank you for agreeing to participate in the Multidisciplinary Cancer Care research study. We will call you at [PHONE #] at [TIME] on [DATE].

Enclosed, you will find:

- A copy of the survey,
- A consent form, and
- A Federal Express envelope.

We ask that you complete the survey before your appointment. As you complete the survey, please note any comments you have on the survey itself. We will ask you about your comments during our interview. After the interview has been completed, a small stipend of $150 will be sent to you in the mail.

Please make a photocopy of your completed survey (with any comments you've included). Using the Federal Express envelope and pre-filled label provided, please mail one copy of your survey to us at least 3 days before your scheduled appointment. You may keep the consent form for your records.

If you have any questions, please contact me at 240-314-5897.

Sincerely,

Martha Popovic
Recruiting Coordinator

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Memo

Attachment 7D: Consent Form

You are being asked to take part in a research study conducted by the National Cancer Institute and the Commission on Cancer. This study is to help us test questions about multidisciplinary care in a cancer setting. The findings from talking to you will help us to improve these questions.

The interview will last about one hour. You will receive $150 as thanks for your time.

Your participation in this study is voluntary. You may choose not to answer any question, and you can stop this interview at any time.

Researchers from the National Cancer Institute and the Commission on Cancer may be observing this interview so they hear your comments about the survey questions.

There are no known risks to you for taking part in this interview. All the data we collect will be kept private. Your name will never be linked to your answers to the questions nor will it appear in any written reports or publications. There are also no direct benefits to you for taking part in this interview, but your answers will help us to correct any problems and make improvements to the survey.

With your permission, I will audio-record the interview. This is in case I missed something in my notes. The recording and all study materials that identify you will be destroyed by June 2011.

If you have any questions about this study, please call Dr. Irene Prabhu Das at NCI, 301-451-5803.

If you have any questions about your rights as a participant in this study, please call Sharon Zack at 301-610-8828.

I have read the information above and:

☐ I agree to participate in the interview.

☐ I agree to have my interview audio-recorded.

Signature: _____ Date: _____

Print Name: _____

Name of Researcher: _____

Attachment 7F: Westat IRB Approval

Date: October 13, 2010

To: Susie McKnutt, Project Director

From: Kerry Levin; Chair, Westat IRB

Subject: **Full Approval of Cancer Survey on Multidisciplinary Care, Project 8372.07.41. FWA5551**

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following**: Cancer Survey on Multidisciplinary Care, Project 8372.07.41.** The Westat IRB reviews all studies involving research on human subjects. This study is sponsored by the National Cancer Institute.

The purpose of this study is to develop a survey instrument that focuses on multidisciplinary cancer care. In order to confirm that the survey questions are easy to understand and answer, Westat will conduct 2 rounds of cognitive interviews with physicians and administrators, mostly those located in hospital settings.

Interviews will be conducted on the telephone and in-person. In all cases, respondents will provide documented informed consent and receive $200 for their participation in the study.

The IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110 (b) (1)]. This study can be considered minimal risk and is approved under expedited authority.

As the Project Director you are responsible for the following:

- If you received a conditional approval, project activities (e.g., recruiting, enrolling, etc.) may not begin until your responses have been received by the IRB and final approval is granted.
- You are required to submit this study for a continuing review on or before **October 13, 2011.**
- In the interim, you are responsible for notifying the IRB Office as soon as possible if there are any injuries to the subjects, problems with the study, or changes to the study design that relate to human subjects.

cc: Institutional Review Board

Susan Crystal Mansour