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Introduction

OMB# 0925-0046-21
Exp. Date: 2/28/2013

The National Cancer Institute's Cancer Therapy Evaluation Program **(CTEP)** and the [INSERT COOPERATIVE GROUP NAME] would like **your opinions about a new NCI clinical trial for [INSERT CANCER TYPE] cancer** not yet open. This trial will be called the **[INSERT TRIAL NAME] trial ([INSERT NCI TRIAL CODE])** and will require patients with [INSERT ONE LINE DESCRIPTION OF PATIENT ELIGIBILITY].

We are soliciting feedback from clinical oncology researchers to **learn any potential issues with opening and accruing** to this trial.

NCI has developed a **brief online survey** to quickly and easily **gather your comments anonymously**.

The **PDF attachment** to your email invitation provides an overview of the [INSERT TRIAL NAME] trial's concept. After reviewing this brief document we ask that you **take 5 minutes** to answer this short survey.

Your comments will help us plan in advance for any concerns about the [INSERT TRIAL NAME] trial identified from this survey. We **thank you** for your assistance!

To continue and begin the survey, click the "Next" button below.

Next -->

If you experience any technical difficulties, please contact the survey administrator at User-Centered Design at survey@user-centereddesign.com

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Privacy Statement and Consent

Your participation in this survey is completely voluntary. Please be assured that your participation in the survey is anonymous and your responses will never be linked or associated with you.

You may skip any questions that you prefer not to answer. You are also free to stop participating at any point during the survey and have your responses deleted by clicking the "Opt out of survey" box at the bottom of each survey page.

This brief survey should only require approximately 5 minutes of your time.

Please click the "Next" button if you consent to taking this survey.

Opt out of survey

Next -->

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 208927974, ATTN: PRA (0925-0046-21). Do not return the completed form to this address.

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Concept Sheet

IMPORTANT:

Please review the 2-page concept sheet attached to the email you received regarding this survey.

You can open a copy of the concept sheet here.
(This document will open in a new tab.)

Opt out of survey

I have reviewed the concept sheet and am ready to begin -->

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Please reply to all questions from the perspective of your site.

1. Please indicate which best describes your site:

- ○ My practice is located within an academic medical center
- ○ My practice is located within an NCI designated cancer center
- ○ My practice is located within a community hospital
- ○ I/We are a free-standing private practice
- ○ Other:

1a. What best describes the size of your community hospital compared to others?

- ○ We are a small-size community hospital (less than 100 beds)
- ○ We are a mid-size community hospital (between 100-250 beds)
- ○ We are a large-size community hospital (more than 250 beds)

2. What type of oncology best describes your expertise?

- ○ Medical oncology
- ○ Surgical oncology
- ○ Radiation oncology
- ○ Gynecologic oncology
- ○ Pediatric oncology
- ○ Other:

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3. Which specialty at your institution would initially see most of the patients potentially eligible for the [INSERT TRIAL NAME] trial (i.e., [INSERT BRIEF PATIENT ELIGIBILITY DESCRIPTION])?

- ○ Medical oncology
- ○ Surgical oncology
- ○ Radiation oncology
- ○ Gynecologic oncology
- ○ Pediatric oncology
- ○ Other (please specify): _____

4. The [INSERT TRIAL NAME] trial has [INSERT #] research questions. For each, Please tell us how scientifically interesting it is to you.

RQ1: [INSERT RESEARCH QUESTION #1 FROM TRIAL DESCRIPTION SHEET]?
How scientifically interesting is this research question to you?

Not at all interesting				Very interesting
○	○	○	○	○

RQ2: [INSERT RESEARCH QUESTION #2 FROM TRIAL DESCRIPTION SHEET, IF APPLICABLE]?
How scientifically interesting is this research question to you?

Not at all interesting				Very interesting
○	○	○	○	○

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5. Assuming the [INSERT TRIAL NAME] trial is completed as planned, what impact do you believe the findings will have on your treatment of [INSERT CANCER TYPE] cancer patients?

Limited impact				High impact
○	○	○	○	○

Please elaborate on your answer:

Opt out of survey

Save and Continue -->

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6. Given what you read in the concept sheet summary, how interested are you in opening the [INSERT TRIAL NAME] trial at your site?

Not at all interested				Very interested
○	○	○	○	○

6a. What are the top reasons why you are not that interested in opening the [INSERT TRIAL NAME] trial? [Select up to 3.]

- ☐ Not scientifically interesting enough
- ☐ Does not match our patient population
- ☐ Limited interest by oncologist(s) here
- ☐ Too many competing trials for this cancer
- ☐ Too great of a burden on patients (e.g., logistics, cost)
- ☐ Too difficult to conduct the study (e.g., burden on staff, coordination required, equipment needed)
- ☐ Financial cost to our site would be too great (e.g., non-reimbursable expenses)
- ☐ Too difficult to accrue patients
- ☐ Concerns about drug availability
- ☐ Other: _____

6b. What are the top reasons why you might be interested in opening the [INSERT TRIAL NAME] trial? [Select up to 3.]

- ☐ Scientifically interesting research question(s)
- ☐ Fills unmet need for our current patient population
- ☐ High level of interest by oncologist(s) in the practice
- ☐ Few competing trials for this cancer
- ☐ Limited burden on patient (e.g., logistics, cost)
- ☐ Ease of doing the study (e.g., limited burden on staff or coordination, have equipment needed)
- ☐ Limited non-reimbursable expenses
- ☐ Availability of study drug(s)
- ☐ Ease in accruing to the trial
- ☐ Other: _____

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7. How difficult do you believe the [INSERT TRIAL NAME] trial will be to open at your site?

Not at all difficult ○ ○ ○ ○ ○ Very difficult

8. For each of the trial's requirements listed below, please tell us whether or not it will make it difficult to open or run the [INSERT TRIAL NAME] trial at your site.

How difficult will this requirement make it to open or run this trial at your site?	Not make it difficult to open/ run the trial	Make it somewhat difficult to open/ run the trial	Make it very difficult to open/run the trial
[INSERT REQUIREMENT #1 FROM DESCRIPTION SHEET]	○	○	○
[INSERT REQUIREMENT #2 FROM DESCRIPTION SHEET]	○	○	○
[INSERT REQUIREMENT #3 FROM DESCRIPTION SHEET]	○	○	○
[... INSERT THROUGH REQUIREMENT #N FROM DESCRIPTION SHEET]	○	○	○

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9. How often do you see a patient who may be eligible for the [INSERT TRIAL NAME] trial (i.e., [INSERT BRIEF PATIENT ELIGIBILITY DESCRIPTION])?

-select-

10. If your site were to open this trial, about how many patients do you believe your site could accrue to the [INSERT TRIAL NAME] trial in a year?

☐ (Number of patients - integers only)

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11. For each of the items below, please tell us whether or not you think it will make it difficult to accrue patients to the [INSERT TRIAL NAME] trial.

How difficult will this issue make it to accrue patients to this trial?	Not make it difficult to accrue patients to the trial	Make it somewhat difficult to accrue patients to the trial	Make it very difficult to accrue patients to the trial
Inclusion/exclusion criteria of the trial	○	○	○
Getting patients referred to the trial	○	○	○
Patients declining to enroll (e.g., unwilling to randomize, prefer one study arm)	○	○	○
Burden on patient to participate in the trial (e.g., logistics, time)	○	○	○
Explaining the trial's details to a patient, including consenting	○	○	○
Cost to the patient (e.g., insurance, reimbursement)	○	○	○

Please tell us in the box below if there are other reasons, not listed above, that might make this trial difficult to accrue patients at your site:

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Save and Continue -->

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12. How many similar trials are open at your site that would compete for the same patient population as the [INSERT TRIAL NAME] trial?

Number of similar trials open at your site from each sponsor (Integers only)	Which sponsor group most competes for the same patient population as this new trial?
☐ # competing trials that are sponsored by NCI (including cooperative group trials)	○
☐ # competing trials that are sponsored by pharmaceutical/biotech industry	○
☐ # competing trials that are investigator initiated trials from academic medical centers	○

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13. Do you have any **final comments** about the [INSERT TRIAL NAME] trial that you would like to share?

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Survey Complete

Thank you for completing this survey!

Your answers have been submitted anonymously.

We appreciate your feedback regarding the [INSERT TRIAL NAME] trial.
Your comments will help ensure that we plan in advance for any concerns identified.

If you would like a summary of the findings after the survey closes, please send an email to 61164thflrlab@mail.nih.gov

You may now close this window.

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