Attachment A OMB # 0925-0046-18

Exp. Date: 1/31/2010

National Cancer Institute
Clinical Trials Accrual Survey – A Needs Assessment

The National Cancer Institute (NCI) has a committed effort to assist with clinical trial accrual. As part of these efforts, the Office of Communications and Education (OCE) is interested in learning about clinical trial accrual communication processes and ways that OCE can provide greater support to those in the field. OCE has worked on a number of research initiatives to improve accrual rates. The goal of these efforts has been to identify effective and promising accrual methods and communication techniques to increase clinical trial participation.

OCE is using this Web-based survey gather formative information to help inform the development of materials and tools that will support increased accrual to clinical trials. The goal of this formative needs assessment is to better understand and prioritize the prevalence of promising practices that support accrual to clinical trials. The data will be collected from persons in the cancer centers who are in a position to know about how accrual functions.

Given your position in a NCI-designated cancer center we appreciate your interest and look forward to receiving your contribution to this important needs assessment. If you have any questions about the survey please do not hesitate to contact XXXXXXXXX.

Thank you in advance. The survey will take about 20 minutes of your time.

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

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

Privacy Statement

Your participation in this survey is completely voluntary. Please be assured that your responses will be kept confidential and will not be disclosed to anyone outside NCI or its contractors, User-Centered Design, Inc. and AED (Academy for Educational Development). All data will be reported in aggregate only and neither your name nor your organization's name will be included in any reports. You may skip any questions that you prefer not to answer or withdraw at any point during the survey. If you choose to withdraw and want to delete your data, simply click the "Delete Survey" link at the top of the page.

[NOTE: FORMATING TBD FOR SURVEY QUESTIONS]

Background Questions on the Respondent and the Respondent's Cancer Center

We would appreciate your sharing some information about your background with us. We will use this to classify your responses. Other information about your Cancer Center accrual rates has been obtained prior to collecting this needs assessment data.

What is your role at this Cancer Center?

- o Cancer Center Director
- o Clinical Trial Coordinating Office Representative
- o Insurance or Clinical Trial Access Representative
- o Head of a disease group (*please specify group*)_____
- o Lead Research Nurse of a disease group (*please specify group*)
  _____

How long have you served in this role at this Cancer Center? _____ years

How long have you been at this Cancer Center overall? _____years

To begin we would like your input on elements of the overall organization and administrative commitment to clinical research and accrual as well as to your cancer center's needs in this area.

Leadership, commitment, and expectations

For each of the following statements, please indicate the response that best represents your opinions for your organization.

1. Clinical research is critical to the mission of the Cancer Center.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

2. Senior cancer center leadership frequently communicates the high priority of clinical research to all Center staff (including those not directly involved in clinical trials).
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

3. The commitment to clinical research by the institution is unquestioned.
   Often
   Occasionally
   Rarely/Never
   DK

4. The contributions that staff make to clinical research receive strong recognition from Center leadership.
   Always
   Most of the time
   Some of the time
   Rarely/Never
   DK

5. How effectively do you feel the Center leadership demonstrates the importance in clinical research by its actions and its words?
   Often
   Occasionally
   Rarely/Never
   DK

6. Center leadership solicits input from all clinical research staff on the mission of the cancer center.
   Often
   Occasionally
   Rarely/Never
   DK

7. Clinical research personnel feel they have few convenient channels or opportunities to discuss the institution's direction with the Center's leadership.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

Mission, vision, and accountability around research and clinical trials

1. How many staff members do you believe could articulate the Center's stated mission AROUND CLINICAL RESEARCH, at least approximately?
   All or nearly all (90%+)
   Over half (60-90%)
   About half (40-59%)
   Less than half (10-39%)
   Very few/None (10% or fewer)
   DK

2. How many research staff members do you feel embrace a strong commitment to the Center's mission?
   All or nearly all (90%+)
   Over half (60-90%)
   About half (40-59%)
   Less than half (10-39%)
   Very few/None (10% or fewer)
   DK

3. All staff understand that investigator initiated clinical trial accruals are central to achieving the center's mission?
   Very much
   Somewhat
   Only a little
   Not at all
   DK

4. PIs and clinic staff understand and value the importance of supporting clinical trial recruitment to trials in other disease sites or modalities?
   Very much
   Somewhat
   Only a little
   Not at all
   DK

Culture

1. If a trial does not achieve its accrual goals, who is responsible:
   - o PI / Disease Site Group
   - o Clinical Trials Office
   - o Other (please specify) _____
   - o Everyone

2. Cross-disease site cooperation in designing and conducting clinical trials occurs.
   Often
   Occasionally
   Rarely/Never
   DK

Policy and Procedures

1. With respect to processes for identifying and recruiting patients for clinical trials, approximately what percent are common to all disease site and modality groups?
   All or nearly all (90%+)
   Over half (60-90%)
   About half (40-59%)
   Less than half (10-39%)
   Very few/None (10% or fewer)
   DK

2. Clinical trial recruitment processes result in higher accruals if they are unique to the disease site.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

3. If your center is part of a larger institution, the institution clearly understands and supports the need for clinical research at the Cancer Center.
   Always
   Most of the time
   Some of the time
   Rarely/Never
   DK

4. How much does patient screening for clinical trials drop on Friday afternoons compared to Monday afternoons?
   Always
   Most of the time
   Some of the time
   Rarely/Never
   DK

Internal communication

1. If a prostate oncologist wished to know what breast cancer studies were underway at your center, they would **most** likely:
   - o Call the breast cancer disease leader
   - o Call a breast cancer PI they knew
   - o Use a central data source supported by the institution (e.g., a web site, a master clinical trial list, etc.)
   - o Go a web search on your center's website
   - o Look back at past monthly newsletters that list trials
   - o Use clinicaltrials.gov
   - o Other (please specify) _____

2. At the current time, all members of multidisciplinary care teams (including oncologists, surgeons, radiation oncologists, and other specialists) actively promote clinical trials to patients.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

3. The Center demonstrates the importance of multi-institutional studies by supplying additional resources in terms of staffing.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

Resource availability (e.g., people, equipment, scheduling, etc.)

1. When compared to the support for basic science by the center, center support for clinical research support is:
   Excessive
   About right
   Too little

2. How frequently is staffing for clinical research a problem at your cancer center?
   Always
   Most of the time
   Some of the time
   Rarely/Never
   DK

3. The Center's resources are allocated optimally to provide the best chance of success in clinical research.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

4. How frequently do resource constraints in a center core (such as statistical support, clinical trials offices, and bio-specimen repositories) impact the opening and management of therapeutic trials.
   Always
   Most of the time
   Some of the time
   Rarely/Never
   DK

Promotional support and marketing for clinical research

1. If a community physician wished to know what GU clinical trials were underway at your center, they would most likely:
   - o Call the breast cancer disease leader
   - o Call a breast cancer PI they knew
   - o Use a central data source supported by the institution (e.g., a web site, a master clinical trial list, etc.)
   - o Do a web search on your center's website
   - o Look back at past monthly newsletters that list trials
   - o Use clinicaltrials.gov
   - o Other (please specify) _____

2. Community physicians frequently complement us on the quality of the information they receive from us about our open and upcoming clinical trials.
   Always
   Most of the time
   Some of the time
   Rarely/Never
   DK

3. Patients who ask about clinical trials frequently bring in NCI pamphlets or educational brochures describing clinical research
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

4. Patients who ask about clinical trials frequently bring in information downloaded from inappropriate web sources
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

5. Patients who ask about clinical trials have been influenced by the information they have independently found through their search of our web site.
   Always
   Most of the time
   Some of the time
   Rarely/Never
   DK

6. If the NCI did better job of marketing of the importance of cancer clinical trials, our accruals would be significantly enhanced.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

7. If the center did a better job of marketing of the importance of cancer clinical trials, our accruals would be significantly enhanced.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

8. Materials used to inform and recruit potential candidates for clinical trials are tailored to the different cultures, languages, and reading levels in the Center's catchment area.
   Very much
   Somewhat
   Only a little
   Not at all
   DK

9. How do you rate the Center's performance in reaching ethnic minority populations with its clinical trials communications?
   Excellent
   Good
   Only fair
   Poor
   DK

In the following sections you will be asked to discuss management of the collection, or portfolio, of clinical trials at your Cancer Center.

Development/Selection of protocols for cancer center participation

1. The Center has regularly scheduled meetings to review the entire portfolio of open trials to ensure that trials are available for as many patients coming to the cancer center as reasonably possible.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

2. A strong clinical trials program demands a a diversity of funding streams for the trials.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

3. Does the Center have a formal, written strategic plan for its clinical trials research?
   Yes
   No
   DK

   3a. (IF YES:) The Center's current trials are strongly is guided by this strategic plan.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

4. The Center has a formal process for determining if trials compete for the same patient population.
   Yes
   No
   DK

5. At our Cancer Center, two or more trials have competed for participants from the same pool of candidates.
   Often
   Occasionally
   Rarely/Never
   DK

6. The scientific review committee requires a statement about the frequency that the types of patients appropriate for a new trial visit are seen at the Center.
   Yes
   No
   DK

7. Does the Center maintain screening logs of:
   a) patients with appointments. [Yes, No, DK]
   b) patients screened for studies. [Yes, No, DK]
   c) patients offered studies. [Yes, No, DK]

8. When compared to tumor boards, the frequency that accruals to open trials are reviewed is:
   Often
   Occasionally
   Rarely/Never
   DK

9. The clinical trials portfolio achieves a good balance between the patient population of the cancer center and investigator interests.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

10. Studies closed for low accrual are formally analyzed to understand why they did not accrue.
    Often
    Occasionally
    Rarely/Never
    DK

11. For open trials, by disease group we measure the ratio of the number of total accruals to the number of open trials.
    Yes
    No
    DK

12. Our procedure for closing trials always trials to remain open excessively than should be the case.
    Strongly agree
    Mostly agree
    Mostly disagree
    Strongly disagree
    DK

13. The scientific review committee gives serious consideration to potential financial and logistical burdens for trial participants when reviewing potential studies.
    Always
    Most of the time
    Some of the time
    Rarely/Never
    DK

14. Our protocols include fair compensation for logistical burdens that arise for trial participants.
    Always
    Most of the time
    Some of the time
    Rarely/Never
    DK

Tracking portfolio performance: Monitoring protocol accrual rates

1. The entire portfolio of open studies by disease site are regularly evaluated and the disease site is accountable for underperforming studies
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

2. The Center analyzes data to identify under-accruing protocols by metrics such as projected vs. actual accrual and time since the last patient accrued.
3. accrue.
   Often
   Occasionally
   Rarely/Never
   DK

4. Formal process improvement techniques are utilized to implement improvements in individual trials, in disease site groups processes, and in overall protocol development, selection, and management.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

Criteria for protocol closure

1. We have an excess of trials with low accrual.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

2. Does the Center have a system for quickly identify under-accruing studies and a system that provides for corrective actions?
   Yes
   No
   DK

In this section we would like to understand your recruitment practices and needs with regard to clinical trials.

Staffing

1. The Center has been unable to maintain the staffing needed to ensure satisfactory clinical trials recruitment.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

2. If I had the authority, rebalance the personnel among disease sites and/or modalities to better match clinical research needs
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

Training and promotion

1. Does the Center have formal mentoring or training programs designed to enhance the communication skills of staff who discuss clinical trials with patients?
   Yes
   No
   DK

2. How do you rate the training/mentoring programs available to clinical trials recruitment personnel?
   Excellent
   Good
   Only fair
   Poor
   DK
   None available

3. Communication with patients about clinical trials is rarely an issue with our staff.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

4. What proportion of new research staff is given orientation in clinical trials policies, procedures, and operations?
   All or nearly all
   Most
   Only some
   Few or none

5. How do they rate the quality (e.g., usefulness, thoroughness) of new staff orientation?
   Excellent
   Good
   Fair
   Poor
   DK

6. How often are staff who work in clinical trials recruitment refreshed in the best approaches to talking with potential recruits?
   Annually
   Every six months
   Quarterly
   On demand
   Never

DK

7. Research staff involved in recruitment to clinical trials receive support from the Center to maintain necessary credentials and certifications.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

8. How frequently does sharing of information, tools, and best practices concerning trial accrual occurs across groups at the Center.
   Very frequently
   Somewhat
   Only a little
   Not at all
   DK

Identifying eligible patients

1. New patients' medical records are reviewed before their clinic visit in order to identify those who may be eligible for a clinical trial.
   Always
   Most of the time
   Some of the time
   Rarely/Never
   DK

2. How often are existing patients on non-trial treatment monitored for recurrence or progression to determine their eligibility for a different clinical trial?
   Often
   Occasionally
   Rarely/Never
   DK

Education—patient by patient (i.e., distributing materials to patients)

1. Information about the importance of clinical research is visibly highlighted in the clinic through such media as prominently placed posters, banners, brochures, etc.
   Very much
   Somewhat
   Only a little
   Not at all
   DK

2. Educational materials aimed at potential recruits are also prepared in multiple languages to accommodate non-English speakers/readers in our area.
   Always
   Most of the time
   Some of the time
   Rarely/Never
   DK

3. We frequently lose potential accruals due to language or culture issues.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

4. Every patient who comes into the center is provided information about clinical trials and, where asked or appropriate, a staff member initiates a conversation to assist the patient's decision, prior to the consenting process.
   Always
   Most of the time
   Some of the time
   Rarely/Never
   DK

In this section we are interested in learning about how your Center uses information technology to support your clinical research and accrual.

1. How much of the Center's clinical trial accruals data is computerized so that it is easily accessible by staff?
   All or nearly all
   Most
   Only some
   Little or none
   DK

2. Do what degree are the Center's clinical trial administrative systems and accrual data integrated to facilitate analysis?
   All or nearly all
   Most
   Only some
   Little or none
   DK

3. Approximately how many different information systems does a clinician need to use to enroll a patient on a clinical trial (1, 2, 3, 4, 5 or more)

In this section we are interested in learning about how you work with health insurance companies, State, and CMS to gain reimbursement for clinical research activities and how this impacts your accrual process.

1. How do your patients rate the Center's ability to provide information and counseling about insurance coverage for clinical trials?
   Excellent
   Good
   Fair
   Poor
   DK

2. The Center has a dedicated financial specialist to assist patients with insurance issues ?
   Yes
   No
   DK

3. Apart from individual patients' cases, the Center actively tries to identify insurance barriers and determine what systemic changes should be made to make it easier for patients to participate in trials.
   Very much
   Somewhat
   Only a little
   Not at all
   DK

4. The Center works with legislators, state, and/or federal government bodies to assist in implementing clinical trial friendly rules and laws.
   Very much
   Somewhat
   Only a little
   Not at all
   DK

   4a. If "very much" or "somewhat", list what actions you have taken to work with legislators, state, and/or federal agencies to promote coverage
   _____

5. Medicare and Medicaid coverage of clinical trials is a problem for our center.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

In this section we ask questions about the activities you have undertaken to conduct community outreach to enhance clinical research accrual.

1. How do you rate the Center's performance in publicizing existing and future clinical trials to community physicians?
   Excellent
   Good
   Fair
   Poor
   DK

2. To what degree is the promotion of clinical trials in the community the responsibility of the PI versus the responsibility of the cancer center
   Mostly PI
   About equal
   Mostly the center
   DK

3. After the trial, center physicians make a point of returning to community oncologists for follow-up.
   Always
   Most of the time
   Some of the time
   Rarely/Never
   DK

4. The Center has a unified procedure for informing referring physicians of the status of referred patients.
   Strongly agree
   Mostly agree
   Mostly disagree
   Strongly disagree
   DK

5. The Center has developed programs to improve the cultural competency of staff to increase participation of under-served populations.
   Very much
   Somewhat
   Only a little
   Not at all
   DK

6. The Center makes translators available to help increase clinical trials participation of non-English speakers.
   Always
   Most of the time
   Some of the time
   Rarely/Never
   DK

General Questions about Clinical Research Accruals at your Cancer Center.

We would appreciate it if you would take the time to answer the following open ended questions about accrual to clinical research at your Cancer Center.

1. What change(s) at your Cancer Center if any, do you think would have the most positive impact on accruals to clinical trials?

2. Can you think of any research related activities or practices that your Center does especially well with respect to accrual that would benefit other cancer centers?

3. Are there any other issues pertaining to clinical research accrual that you would like to share with us?

Thank you for your participation