

Cancer Clinical Investigator Team Leadership Award for FY 2012

Participating Organizations

National Cancer Institute (www.nci.nih.gov)

Title: Cancer Clinical Investigator Team Leadership Award

This is a reissue of the FY2011 administrative supplement award announcement. Several modifications have been made in the current announcement, so please review the complete announcement carefully.

Key Dates

Letter of Intent Receipt Date: March 2, 2012

Application Receipt Date: March 23, 2012

Anticipated Start Date: No later than September 30, 2012

Background and Purpose

In 2005, the NCI began implementing a plan to restructure its clinical trial enterprise in order to realize the promise of molecular medicine to advance oncologic clinical practice. This restructuring plan <http://transformingtrials.cancer.gov/files/ctwg-report.pdf> (June 2005) is outlined in a document produced by the Clinical Trials Working Group (CTWG). One of the plan's 22 initiatives is to realign NCI funding, academic recognition, and other incentives in order to promote collaborative team science and clinical trial cooperation. The initiative supports creating "new forms of recognition for Cancer Clinical Investigators" and a new "Cancer Clinical Investigator Team Leadership Award." This administrative supplement award supports, acknowledges, and recognizes outstanding clinical investigators whose participation and activities promote a culture of successful clinical research. The award is also intended to promote the retention of clinical investigators in academic clinical research careers. It is the intent of the Cancer Clinical Investigator Team Leadership Award to support mid-level clinical investigators at NCI-designated Cancer Centers who are participating extensively in NCI-funded collaborative clinical trials.

Funds Available and Allowable Costs

The intent of this award is to provide partial salary support for up to 10 clinical investigators at NCI-designated Cancer Centers through administrative supplements to P30 Cancer Center Support Grants. The total supplemental budget should not exceed \$50,000 (total costs) per year for a total of two years, including salary, fringe benefits, and associated facilities and administrative costs.

It is expected that the awardee will devote 10-15% effort to the activities associated with this award and that the sponsoring institution will protect the awardee's time for these activities.

Funds from this award may not be used for salary for mentors, secretarial and administrative assistance, equipment, or research supplies. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (<http://grants.nih.gov/grants/policy/policy.htm>).

Allowable costs include:

- Salary, fringe benefits, and associated facilities and administrative costs.
- Courses, seminars, meetings, conferences, and workshops that support the intent of this award. The description of activities and projects planned under this award (to be included in application packet) should include details of relevant activities and justify how participating in the respective activities helps the nominee meet the intent of this award.
- Travel (up to \$2500/year) to attend courses, seminars, meetings, conferences, and workshops: In the budget justification, include the destination, dates or duration of your stay for all anticipated travel. It is important that you clearly state how the travel is directly related to the intent of this award. You should refer to your institution's travel policy for guidance on how you should arrange the travel, but if your institution lacks a policy, it is expected that you will follow the U.S. federal government policy found here: <http://www.gsa.gov/federaltravelregulation>.

Support provided under this supplemental award is not transferable to another investigator or institution.

Eligible Institutions and nominees

Only NCI-designated Cancer Centers participating in NCI-funded collaborative clinical trials that did not receive the first year of this two-year administrative supplement award in FY 2011 are eligible to submit an application. Note that NCI-designated Cancer Centers receiving the first year of this two-year administrative supplement in FY 2010 are permitted to re-apply at this time, but must nominate a different nominee for the award. Questions about eligibility should be directed to the NCI Program Director assigned to your P30 Cancer Center Support Grant (CCSG).

Nomination: The nominee must be nominated by the Cancer Center Director (Principal Investigator (PI) of the P30 CCSG) on the basis of qualifications, interests, accomplishments, and motivation, and based upon the nominee's intent and ability to promote a successful clinical research culture and to pursue an academic career in clinical research.

Only NCI-designated Cancer Centers participating in NCI-funded collaborative clinical trials that did not receive this administrative supplement award in FY 2009 are eligible to submit an application.

Number of Applications

Each eligible NCI-designated Cancer Center can submit only one application.

Eligibility Criteria for Clinical Investigator Nominees (must be met at the time of application)

1. Must be currently practicing in the oncology clinical setting and have the potential for leadership of the Cancer Center's clinical trials. For example, setting clinical research priorities; overseeing clinical trials; submitting protocols to the IRB; monitoring adverse event reporting; and increasing enrollment in NCI-funded clinical trials.
2. Must be a full-time faculty member (academic or clinical track) at the assistant or associate professor level, eligible for promotion/tenure or with permanent status (if such activities are generally available to individuals at the applicant institution).
3. Must be either:
 - o Physician (e.g., M.D., D.O.)
 - o Oncology nurse, clinical psychologist, or similarly qualified clinician with a doctoral degree
4. Must be practicing >3 years post-fellowship and board certified in their specialty area, e.g., medical oncology, radiation oncology, oncology nursing, surgical oncology or equivalent.
5. Must be engaged in the conduct of NCI-funded cancer clinical trials at an academic medical center;
6. Must not currently serve or have previously served as a Principal Investigator of an NIH R, K, or P series grant (http://grants.nih.gov/grants/funding/funding_program.htm) (with the exception of mentored K01, K07 Development Award, K08, and K23 recipients), or as a leader of a component research project of a Program Project award, or a co-leader of component research project of a SP0RE award.
7. Must be a U.S. citizen or non-citizen national, or must have been lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-551) or some other verification of legal admission as a permanent resident.
8. Nominee cannot have received this award previously.

Application Procedure:

1. **Cover Letter:**

A cover letter, signed by the PI of the P30 CCSG, must accompany each application. The cover letter should include:

 - a. The name of the nominee.
 - b. The process used to select the nominee.

c. Statement verifying that the nominee meets the eligibility criteria of the award.

2. **Format of the Application:**

The application should include:

- 1) The standard face page of the PHS 398 (revised 6/2009)
<http://grants.nih.gov/grants/funding/phs398/phs398.html>
- 2) A biographical sketch of the Clinical Investigator nominee that includes all sources of current, pending, and past support.
- 3) A brief (no longer than 2-pages) outline and description of activities and projects planned under this award, including a timeline.

Examples of projects and activities considered appropriate to this award include, but are not limited to (projects/activities listed below are not ordered by priority or importance):

- Organizing courses, lecture/seminar series, educational sessions, or workshops for clinical research staff, patient advocates, patients, and other stakeholders which contribute to building or enhancing a culture of clinical research at the awardee's institution.
- Attending courses, seminars, meetings, conferences, or workshops that enhance the awardee's ability to contribute to a successful clinical research program at his/her institution.
- Engaging fellows and new faculty in collaborative clinical research efforts at the awardee's institution.
- Mentoring junior staff/fellows/trainees.
- Participating on a particular cancer center committee (i.e., Institutional Review Board (IRB)) that enhances the awardee's clinical research knowledge or leadership.
- Developing a clinical trial concept and/or protocol.
- Designing and implementing initiatives to better coordinate, support and integrate a clinical trials culture at the institution.
- Developing streamlined processes for the awardee's institution's (IRB), Data Safety Monitoring Board (DSMB), or Scientific Review Committees.
- Resolving activation or accrual issues for a trial at the awardee's institution.

An award can support multiple projects/activities as time, effort, and resources allow.

- 4) A 3-5 page narrative that addresses the review criteria at the end of this document, including:
 - How the nominee's training, experience, current activities, and planned activities under this award will support promotion of a successful clinical research culture at his/her institution.
 - The nominee's involvement in past and present NCI-funded cancer clinical trials at academic medical centers and clinical trial-related activities.
 - The nominee's plans for a career in academic clinical research.
- 5) A budget entered on budget pages 4 and 5 of PHS 398 (revised 6/2009) for the calendar months of effort for the Clinical Investigator during the first and second year, with appropriate justification.
- 6) **Letters of Support:** Three signed letters of support should be submitted on behalf of an individual's application with all copies of the application. Letters should include a description of the academic status of the applicant and any additional support provided by the institution. At least one of the letters of support should be an institutional support letter from the Department Chair or appropriate institutional official which indicates the institution's level of commitment to fostering the nominee's career as a clinical investigator in an academic clinical research career, as reflected by the extent to which

the nominee will have dedicated time for activities proposed in the application. The letter(s) must demonstrate a commitment to allow at least 10% effort for activities proposed in the application.

Letter of Intent to Submit an Application:

To expedite the review process, you are requested to notify the Office of Cancer Centers of your intent to apply for this administrative supplement. Notification should be provided by e-mail no later than March 2, 2012 to:

Ms. Nga Nguyen
Program Analyst, Office of Cancer Centers
National Cancer Institute
nguyenn2@mail.nih.gov

Where to Send the Cover Letter, Application, and Letters of Support

Applications are due no later than March 23, 2012.

Email an electronic copy of the application in PDF format, including the cover letter and letters of support, to both program staff listed below.

Ms. Nga Nguyen
Program Analyst, Office of Cancer Centers
National Cancer Institute
nguyenn2@mail.nih.gov

Dr. Jennifer Hayes
Program Director, Coordinating Center for Clinical Trials
National Cancer Institute
hayesjf@mail.nih.gov

Review Criteria There is no predetermined weighting for the categories of review criteria. Bulleted items in each category serve as examples for addressing review criteria. An application does not need to be strong in all areas to receive a meritorious assessment.

Nominee's training and experience

- Does the nominee have formal training strongly supporting a clinical leadership role in oncology research?
- Does the nominee have experience strongly supporting a clinical leadership role in oncology research?
- Does the nominee have leadership experiences in one or more clinical research activities such as institutional or multi-center clinical trials, a cancer center clinical trials office, an Institutional Review Board, a Data Safety Monitoring Board, or a Cooperative Group or network?
- Has the nominee participated in NCI-sponsored collaborative clinical trials such as those funded through the Cancer Therapy (CTEP), Community Clinical Oncology Program (CCOP), Cancer Centers or Specialized Programs of Research Excellent (SPORE) programs?

Nominee's current activities to promote successful clinical research programs at his/ her institution

- How does the nominee serve as a critical supporter of the overall clinical research mission at his or her institution?
- How does the nominee mentor or guide trainees, junior investigators, as well as pharmacy, nursing, clinical research and other staff, and patients/patient advocates in support of clinical trial activities?
- To what extent is the nominee currently involved in clinical research activities such as institutional or multi-center clinical trials, a Cooperative Group or network, a cancer center clinical trials office, an Institutional Review Board, a Data Safety Monitoring Board, adverse event monitoring, or enhancing clinical trial enrollment?
- To what extent is the nominee currently involved with NCI-sponsored collaborative clinical trials such as those funded through the CTEP, CCOP, Cancer Centers or SPORE programs?
- What is the breadth of the nominee's sphere of involvement for clinical trials research at his or her institution? For example, does his or her impact cross disease sites, modalities, and departments?

Nominee's planned activities to promote successful clinical research programs at his/her institution

- How would this award permit the nominee to continue current activities or develop new activities related to promoting successful clinical research that otherwise would not be possible?
- To what extent do the activities proposed in the application promote and/or enhance a successful clinical research culture?
- To what extent do the activities proposed in the application promote retention of the nominee in an academic clinical research career?

Institutional commitment to support the nominee's planned activities and career in clinical research

- How does the nominee's institution intend to continue to provide or augment its support for him/her to promote successful clinical research at its cancer center?
- Is there clear commitment of the institution to relieve the nominee of sufficient duties to allow at least 10% effort for activities proposed in the application?
- Is the level of institutional commitment to the career development of the nominee appropriate to be considered for this award?

Reporting Requirements: A separate progress report will be required 60 days prior to the anniversary date of the supplemental award. A separate final report will also be required 30 days following the supplemental award's conclusion.

The progress report and final report should include:

- Details on the progress and outcome of activities and projects listed in the application.
- Awards and honors received during the performance period related to activities under this award.
- Publications, journal articles, and patents related to this award.
- Impact to date of the award on career development.
- Opportunities that otherwise would not have been possible without the award.
- Near and longer term effect(s) of the award on the institution or other staff.

Publications resulting from this award should acknowledge the funding source as follows: *"This study was supported in whole or in part by funding from the Cancer Clinical Investigator Team Leadership Award awarded by the National Cancer Institute" though a supplement to P30 xxxxxxx.*

Publications, journal articles, and/or patents produced under an NIH award-supported project must bear an acknowledgment and disclaimer, as appropriate, as provided in NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards Section 8.2 "Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources."

NCI Contact

For programmatic questions concerning this supplement, contact the NCI Program Director assigned to your P30 Cancer Center Support Grant.

Questions regarding fiscal and administrative matters should be addressed to the Grants Specialist for your Cancer Center, NCI Office of Grants Administration. — *posted 3/02/2012*