

Cancer Clinical Investigator Team Leadership Award for Fiscal Year (FY) 2014

Department of Health and Human Services

Participating Organizations

National Cancer Institution (NCI) (<http://www.nci.nih.gov>)

Title: Cancer Clinical Investigator Team Leadership Award (CCITLA)

This is a reissue of the FY 2013 administrative supplement award announcement.

Key Dates

Letter of Intent Receipt Date: February 21, 2014

Application Receipt Date: March 21, 2014

Anticipated Start Date: CCITLA supplements must cycle with the Cancer Center parent award. Therefore, supplements will start on the FY 2014 anniversary date of Cancer Center grants with budget period start dates from June 1 through September 1, 2014. Supplements for Cancer Center grants with budget periods cycling between December 1 and May 1 will begin on the start date of the FY 2015 award, contingent on the availability of FY 2015 funds.

Award Information

The Cancer Clinical Investigator Team Leadership Award (CCITLA) is an administrative supplement award which **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 CCITLA 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

NCI anticipates awarding CCITLA supplements to Cancer Centers with June 1 through September 1 cycle dates with FY 2014 funds and CCITLA supplements to Cancer Centers with December 1 through May 1 cycle dates with FY 2015 funds, contingent upon the availability of FY 2015 funds.

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 (CCSGs). 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.

The nominee must devote 15% - 20% effort to the activities associated with this award and the sponsoring institution **must** protect the awardee's time for these activities.

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>).

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

Allowable costs are limited to:

- Salary (for nominee only), fringe benefits, and associated facilities and administrative costs.
- Travel (up to \$2500/year) and registration fees (for nominee only) to attend courses, seminars, meetings, conferences, and workshops that support the intent of this award. 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.

Funds from this award may not be used for:

- Research-related costs, including but not limited to research supplies, computers, equipment, core facility fees, or sample or data analysis
- Salary for personnel other than the nominee
- Secretarial or administrative assistance and supplies

Eligible Institutions and nominees

Only NCI-designated Cancer Centers participating in NCI-funded collaborative clinical trials are eligible to apply for this supplement. Cancer Centers that received the first year of a two-year CCITLA supplement in FY 2013 are not eligible to submit an application for this announcement. Eligible NCI-designated Cancer Centers that have previously received a CCITLA supplement must nominate an individual who has never received this award. Questions about eligibility should be directed to the NCI Program Director assigned to your P30 CCSG. For a list of past awardees, please refer to: <http://transformingtrials.cancer.gov/home>.

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.

Number of Applications

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

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

- Must be currently practicing in the oncology clinical setting.
- Must 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.
- 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). **A full professor, or anyone above the associate professor level, regardless of tenure status, is not eligible to be nominated.**
- Must be either:
 - Physician (e.g., M.D., D.O.)
 - Oncology nurse, clinical psychologist, or similarly qualified clinician with a doctoral degree
- Must be practicing at least 3 years but no more than 10 years from initial post-fellowship instructor-level/academic appointment.
- Must be board certified in specialty area, e.g., medical oncology, radiation oncology, oncology nursing, surgical oncology or equivalent.
- Must be engaged in the conduct of NCI-funded cancer clinical trials at an academic medical center.
- Must be a U.S. citizen, or non-citizen national possessing a United States passport that delineates and certifies status as a national but not a citizen

of the United States, or must have been lawfully admitted for permanent residence and possess a valid Alien Registration Receipt Card (I-551).

- Cannot have received this award previously.
- Cannot be employed by a Cancer Center that received the first year of a two-year CCITLA supplement in FY 2013.
- Must not currently serve or have previously served as:
 - A Principal Investigator of an NIH R, K, P, U, T, DP, RC, SC or TU series grant (http://grants.nih.gov/grants/funding/funding_program.htm; <http://deainfo.nci.nih.gov/flash/awards.htm#P01>), with the exception of career development awards or mentored awards where the PI is required to be mentored by another investigator (i.e., K01, K07, K08, or K23 mentored career development awards).
 - A project leader or co-leader of a research project within a P01/U19 (Program Project Grant/Research Program Cooperative Agreement).
 - A project leader or co-leader of a research project within a P50 (SPORE) or other P series grant.
 - In the nominee's biosketch in the section listing all sources of current, pending, and past support, **for any NIH P and U series grants and agreements**, indicate that the nominee is NOT a project leader or co-leader of a research project within the grant or agreement, as project leaders/co-leaders in these series of grants are not eligible to be nominated for this award.
 - Questions about eligibility related to the above criteria should be directed to the NCI Program Director assigned to your P30 CCSG.
- Recipients of the ASCO Career Development Awards ARE eligible and may be nominated for this award.

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 (in the order listed):

- 1) The standard face page of the PHS 398 (<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. For each source of support, indicate if the nominee is a Principal Investigator/co-Principal Investigator.
- 3) 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.
- 4) 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 (e.g., 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.

- 5) A budget entered on budget pages 4 and 5 of PHS 398 (<http://grants.nih.gov/grants/funding/phs398/phs398.html>) for the calendar months of effort for the Clinical Investigator during the first and second year, with appropriate justification. 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.
- 6) The checklist form page of the PHS 398 (<http://grants.nih.gov/grants/funding/phs398/phs398.html>).
- 7) **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 15% - 20% 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. The notification is for program planning purposes and will not be included in the review packet. The notification should state the name of the Cancer Center, intent to apply for this award, the name of the Cancer Center Clinical Investigator Nominee, and the name and institutional affiliations of the individuals who will provide letters of support. Notification should be provided by e-mail no later than February 21, 2014 to:

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

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

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

Applications are due no later than March 21, 2014.

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 meet the intent of the award in that he/she is a mid-level (practicing at least 3 years but no more than 10 years from initial post-fellowship instructor-level/academic appointment) clinical investigator participating extensively in NCI-funded collaborative clinical trials?
- Does the nominee have formal training and experience strongly supporting a clinical leadership role in oncology research?

- Does the nominee have leadership experiences in one or more clinical research activities (e.g., institutional or multi-center clinical trials, a cancer center clinical trials office, an Institutional Review Board, a Data Safety Monitoring Board, a Cooperative Group, or CCOP)?
- Has the nominee participated in NCI-sponsored collaborative clinical trials such as those funded through the Cancer Therapy Evaluation Program (CTEP), Division of Cancer Prevention (DCP), Community Clinical Oncology Program (CCOP), Cancer Centers, or Specialized Programs of Research Excellence (SPORE) program?

Nominee’s current activities to promote a successful clinical research culture at his/her institution

- How does the nominee serve as a critical supporter and promoter 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 (e.g., 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, DCP, CCOP, Cancer Centers, or SPORE programs?
- Does the nominee’s involvement and influence in clinical trials research at his or her institution cross disease sites, modalities, and departments?

Nominee’s planned activities to promote a successful clinical research culture 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 beyond the award performance period?
- Is there clear commitment of the institution to relieve the nominee of sufficient duties to allow 15% - 20% 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: An annual and final progress report for the CCITLA supplement must be included as a separately labeled section in the annual progress report for the Cancer Center grant. In addition, a mid-year progress report will be required six months after the award of the supplement.

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 xxxxxx.*

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 Contacts

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.