

Cancer Clinical Investigator Team Leadership Award for Fiscal Year (FY) 2016

Department of Health and Human Services

Participating Organizations

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

Title: Cancer Clinical Investigator Team Leadership Award (CCITLA)

This is a reissue of the FY 2015 administrative supplement award announcement.

Please note the following modifications in the current announcement:

- The (submission) due dates for the Letter of Intent and Application are several months earlier than in past application cycles.
- Awards are anticipated to start in March – September 2016, depending on the Cancer Center's P30 start date.

Key Dates

Letter of Intent Due Date: November 6, 2015

Application Due Date: December 4, 2015

Earliest Start Date: March 2016 for Cancer Centers with P30 Cancer Center Support Grants (CCSGs) with start dates of December through March.

For Cancer Centers with P30 CCSGs with start dates of April through September, the anticipated start date is the 2016 start date of the parent P30 CCSG.

Award Information

The Cancer Clinical Investigator Team Leadership Award (CCITLA) is an administrative supplement award which recognizes and supports clinical investigators with an outstanding record of developing and promoting a culture of successful clinical research. 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** and clinical research efforts. The award is also intended to retain clinical investigators in academic clinical research careers. A candidate for the CCITLA must be nominated by the Cancer Center Director.

The Recalcitrant Cancer Research Act of 2012 (HR 733 / S 362 / S 3566; 112th Congress; Public Law No. 112-176) (**RCRA**)

(<http://legislative.cancer.gov/topics/bill?BillID=7A99A2E5-AF49-4E43-B1F8-F6139BB60531>) calls upon the NCI to “develop scientific frameworks that will help

provide the strategic direction and guidance needed to make true progress against recalcitrant or deadly cancers.” Recalcitrant cancers are defined as those cancers with a five-year relative survival rate below 50 percent. In response, the NCI developed scientific frameworks to enhance the study of pancreatic ductal adenocarcinoma (PDAC) (<http://deainfo.nci.nih.gov/advisory/ctac/workgroup/pc/PDACframework.pdf>) and small cell lung cancer (SCLC) ([http://deainfo.nci.nih.gov/advisory/ctac/workgroup/SCLC/SCLC Congressional Response.pdf](http://deainfo.nci.nih.gov/advisory/ctac/workgroup/SCLC/SCLC_Congressional_Response.pdf)).

Consistent with the NCI’s interest in recalcitrant cancers, applications with candidates whose clinical research focuses on PDAC or SCLC are encouraged, but not required.

Funds Available and Allowable Costs

The NCI intends to provide partial salary support for clinical investigators at up to 10 NCI-designated Cancer Centers through administrative supplements to P30 CCSGs. The total supplemental budget should not exceed \$60,000 (total costs) per year for a total of two years, including salary, fringe benefits and associated facilities and administrative costs.

The candidate must devote 15 to 20 percent effort to the activities associated with this award and the sponsoring institution **must** protect the awardee’s time for these activities. Although cost sharing is not required, institutions are encouraged to cost share if needed to attain 20 percent effort for the candidate.

All awards are subject to the terms and conditions of the CCSG notice of grant award and cost principles and other considerations described in the NIH Grants Policy Statement (<http://grants.nih.gov/grants/policy/nihgps/index.htm>).

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

Allowable costs are limited to:

- Salary (for candidate only), fringe benefits, and associated facilities and administrative costs.
- Travel (up to \$2500/year) and registration fees (up to \$2500/year for candidate 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 stay for all anticipated travel. It is important to clearly state how the travel directly relates 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 candidate,
- Secretarial or administrative assistance and supplies.

Questions about allowable costs should be directed to the NCI Coordinating Center for Clinical Trials (CCCT) CCITLA Program Director, Jennifer Hayes (hayesjf@mail.nih.gov).

Eligibility Criteria for Institutions and Candidates

- 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** payment of a two-year CCITLA supplement in 2015 (2015 CCITLA Award Recipients) are **not eligible** to submit an application for this announcement.

Questions about eligibility should be directed to the NCI CCCT CCITLA Program Director, Jennifer Hayes (hayesjf@mail.nih.gov). Only individuals who have never received this award may be nominated. For a list of past awardees, please refer to: http://www.cancer.gov/about-nci/organization/ccct/other-programs/ccitla/CCITLARecipients_2015.

Nomination: The candidate must be nominated by the Cancer Center Director (Principal Investigator (PI) of the P30 CCSG) based on the candidate's qualifications, **involvement in NCI-funded clinical trials**, interests, accomplishments, motivation, ability to promote a successful clinical research culture and plan 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 the Clinical Investigator

All criteria must be met at the time of the application submission deadline (December 4, 2015) to be considered for the award.

- The candidate must be one of the following:
 - Physician (e.g., M.D., D.O.),
 - Oncology nurse, clinical psychologist or similarly qualified clinician with a doctoral degree. (**A candidate in these disciplines is not required to have a M.D. or D.O. degree to be eligible.**)
- Board certified in specialty area, e.g., medical oncology, radiation oncology, oncology nursing, surgical oncology or equivalent.
- Currently practicing in the oncology clinical setting.
- Practicing at least 3 years but no more than 10 years from initial post-fellowship instructor-level academic appointment as of application submission deadline (December 4, 2015).

- 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.**
- Engaged in the conduct of NCI-funded cancer clinical trials at an academic medical center.
- Potential for leadership of the Cancer Center's clinical trials. For example, setting clinical research priorities; overseeing clinical trials; submitting protocols to the Institutional Review Board (IRB); monitoring adverse event reporting; and increasing enrollment in NCI-funded clinical trials.
- 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 Green Card/Alien Registration Receipt Card (Form I-551).
- Cannot have received the CCITLA previously (applies to the candidate only, not the Cancer Center).
- Not currently or previously:
 - A Principal Investigator of a National Institutes of Health (NIH) R, K, P, U, T, DP, RC, SC or TU series grant (http://grants.nih.gov/grants/funding/funding_program.htm), with the exception of career development awards or mentored awards where the PI is required to be mentored by another investigator (e.g., K01, K07, K08, K18, K22, K23, K25, or K99 mentored career development awards).
 - A project leader or co-leader of a research project within a P or U series grant (e.g., P01 Program Project Grant, U19 Research Program Cooperative Agreement, P50 Specialized Center Grant).
 - The candidate's biographical sketch should include current, pending, and past support, **for any NIH P or U series grants and** indicate that the candidate is NOT a project leader or co-leader of a research project within these grants.
- Recipients of ASCO Career Development Award ARE eligible and may be nominated for this award.

Application Procedure:

1. **Cover Letter** (no longer than 2 pages):
A cover letter, signed by the PI of the P30 CCSG, must accompany each application and include:

- the name of the candidate,
- the process used to select the candidate and why the candidate should receive this award,
- statement verifying that the candidate meets the eligibility criteria of the award.

2. Body 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 candidate. The Biographical Sketch Format Page is available at <http://grants.nih.gov/grants/funding/424/index.htm#format>.

Following the EDUCATION/TRAINING section of the Biographical Sketch, complete sections A, B, C and D as indicated below.

NOTE: Applicants must follow the formats and instructions below.

A. Personal Statement: Briefly describe why your experience and qualifications make you particularly well-suited to receive the CCITLA.

B. Positions and Honors: List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Selected Peer-reviewed Publications and Patent Citations: NIH encourages applicants to limit the list of selected peer-reviewed publications, manuscripts in press, and patent citations to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications recently published, and/or based importance to the field, and/or relevance to the proposed research. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at:

http://publicaccess.nih.gov/submit_process_journals.htm. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material).

D. Research Support: List all ongoing, completed and pending research projects (Federally or non-Federally-supported), indicating if the candidate

is/was a Principal Investigator/co-Principal Investigator. **For any NIH P and U series grants, indicate that the candidate is/was NOT a project leader or co-leader of a research project within the grant.**

- 3) A narrative (3 - 5 pages) that addresses the review criteria at the end of this document, including:
 - How the candidate'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 candidate's involvement in past and present NCI-funded cancer clinical trials at academic medical centers and clinical trial-related activities.
 - The candidate's plans for a career in academic clinical research.
- 4) An outline (no longer than 2 pages) 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 (Note: projects/activities listed below are not ordered by priority):

- 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 committees (e.g., IRB, Data Safety Monitoring Board, Protocol Review and Monitoring Committee, or Scientific Review Committee).
- 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 stay for all anticipated travel. It is important to 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 the application (please append letters after the PHS 398 Checklist in the PDF 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 that indicates the institution's level of commitment to fostering the candidate's career as an academic clinical investigator, as reflected by the extent to which the candidate will have dedicated time for activities proposed in the application. This letter must demonstrate a commitment to allow 15 to 20 percent effort for activities proposed in the application.

Letter of Intent to Submit an Application:

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NCI staff to estimate the potential review workload and plan the review.

Prospective Cancer Center applicants are asked to submit a letter of intent that includes the following information:

- intent to apply for this administrative supplement
- title of this funding opportunity
- name of the Cancer Center and Cancer Center Director (PI of the P30 CCSG)
- name and email address of the Candidate
- names and institutional affiliations of the three individuals providing letters of support for the application

The letter of Intent should be provided by e-mail no later than November 6, 2015 to:

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

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 December 4, 2015.

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

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

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

Candidate's training and experience

- Does the candidate meet the intent of the award in that he/she is a clinical investigator participating extensively in **NCI-funded** collaborative clinical trials who has been practicing at least 3 years but no more than 10 years from initial post-fellowship instructor-level academic appointment as of the application submission deadline?
- Does the candidate have formal training and experience strongly supporting a clinical team leadership role in oncology research?
- Does the candidate have leadership experiences in one or more clinical research activities (e.g., institutional or multi-center clinical trials, cancer center clinical trials office, IRB, Data Safety Monitoring Board, Protocol Review and Monitoring Committee, Scientific Review Committee, involvement in the NCI National Clinical Trials Network (NCTN) or the NCI Community Oncology Research Program (NCORP)?

- Has the candidate participated in **NCI-sponsored** collaborative clinical trials such as those funded through the Division of Cancer Treatment and Diagnosis (DCTD), Division of Cancer Prevention (DCP), Division of Cancer Control and Population Sciences (DCCPS), Office of the Director (OD) or Cancer Centers?

Candidate's current activities to promote a successful clinical research culture at his/her institution

- How does the candidate serve as a critical supporter and promoter of the overall clinical research mission at his or her institution?
- To what extent does the candidate 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 candidate currently involved in clinical research activities (e.g., institutional or multi-center clinical trials, cancer center clinical trials office, IRB, Data Safety Monitoring Board, Protocol Review and Monitoring Committee, Scientific Review Committee, streamlining clinical trial processes, enhancing clinical trial enrollment, involvement in the NCTN or NCORP)?
- To what extent is the candidate currently involved in **NCI-sponsored** collaborative clinical trials such as those funded through the DCTD, DCP, DCCPS, OD or Cancer Centers?
- Does the candidate's involvement and influence in clinical trials research at his or her institution cross disease sites, modalities, or departments?

Candidate's planned activities to promote a successful clinical research culture at his/her institution

- How would this award permit the candidate to expand 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 clinical trials and a successful clinical research culture at the candidate's cancer center?
- To what extent do the activities proposed in the application promote retention of the candidate in an academic clinical research career?
- Does the application indicate appropriate commitment of time and effort for the proposed activities?

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

- Does the candidate's institution intend to continue to provide or augment its support for the candidate to promote clinical research beyond the award performance period?
- Is there clear commitment of the institution to relieve the candidate of sufficient duties to allow the effort (at least 15 percent) for activities proposed in the application?
- Is the level of institutional commitment to the career development of the candidate appropriate to be considered for this award?

Reporting Requirements: A progress report for the CCITLA supplement must be included as a separately labeled section in the annual progress report for the Cancer Center grant for any reporting period for which CCITLA supplemental funds are received.

The progress 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 the candidate's career development.
- Opportunities that otherwise would not have been possible without the award.
- Value added by the award (e.g., for 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.