## Program Guidelines for the National Cancer Institute (NCI) Cancer Clinical Investigator Team Leadership Award (CCITLA) for Fiscal Year (FY) 2019

#### Contents

Modifications in the current announcement:	1
Key Dates	2
Award Information	2
Funds Available and Allowable Costs	3
Eligibility Criteria for Institutions	4
Eligibility Criteria for Clinical Investigator Candidates	4
Tips for Applicants	6
Application	6
Letter of Intent	9
Where to Send the Cover Letter and Application	10
Reporting Requirements	10
Review Criteria	11
NCI Contact Information	13
Appendix A. Instructions and Template for Clinical Trials Table	14

# Please note the following modifications from the FY 2018 administrative supplement award guidelines:

- (Page 5) Current or past Principal Investigators (PIs) of a National Institutes of Health (NIH) peer-reviewed **research** grant of at least \$125,000 in direct costs per year for a minimum of 3 years, <u>with the exception of</u> career development awards/mentored awards where the PI is required to be mentored by another investigator, are not eligible to be nominated.
  - This replaces the eligibility language regarding PIs of specific NIH series grants.
- (Page 6) The required components of the application's cover letter have been updated.
- (Page 7) A table listing clinical trials which the candidate is or has been involved in must be included in the application.
- (Page 7) The Narrative section is now referred to as Qualifications and Career Plan. The instructions for this section have been updated and made more specific.
- (Page 8) The instructions for the Planned Activities have been updated.
- (Page 11) The review criteria have been updated to reflect changes in the application requirements.

## **Key Dates**

Letter of Intent Due Date: November 19, 2018

Application Due Date: by 5:00 PM local time of applicant organization on

December 7, 2018

Earliest Start Date: March 2019 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 2019 start date of the parent P30 CCSG.

#### Award Information

The Cancer Clinical Investigator Team Leadership Award (CCITLA) is an administrative supplement which recognizes and supports outstanding clinical investigators who develop and promote a culture of collaborative clinical trials. It is the intent of the CCITLA to support mid-level clinical investigators at NCI-designated Cancer Centers who participate extensively and collaboratively in **NCI-funded clinical trials**. This award is intended to recognize and support efforts in interventional trials and not intended to support efforts in observational or registry studies. The award is designed to promote the retention of clinical investigators in academic clinical research careers. A candidate for the CCITLA must be nominated by the Cancer Center Director. A successful candidate will have played a critical role in the development of NCI-funded clinical trials at the cancer center and have a record of service on institutional clinical trial committees and in clinical trial-related activities.

A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to groups that receive one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (<a href="https://grants.nih.gov/policy/clinical-trials/definition.htm">https://clinicaltrials.gov/ct2/about-studies/glossary</a>). Clinical trials test new methods of screening, prevention, diagnosis, or treatment of a disease (<a href="https://www.cancer.gov/publications/dictionaries/cancer-terms">https://www.cancer.gov/publications/dictionaries/cancer-terms</a>).

An intervention is defined as a treatment, procedure, or other action taken to prevent or treat disease, or improve health in other ways. Interventions include drugs, vaccines, medical procedures (such as radiation therapy and surgery), medical devices, behavior changes (such as diet and exercise), education programs, and counseling (https://www.cancer.gov/publications/dictionaries/cancer-terms).

#### **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 at least 15% (1.8 calendar months) 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 greater than 15% 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 at NCICCITLA@mail.nih.gov.

#### **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 trials culture and plans to pursue an academic career in clinical

research. This award is intended to recognize and support efforts in interventional trials and not efforts in observational or registry studies. Individuals who have previously received this award **may not be nominated**. For a list of past awardees, please refer to:

https://www.cancer.gov/about-nci/organization/ccct/funding/ccitla.

## **Number of Applications**

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

## **Eligibility Criteria for Institutions**

 Only NCI-designated Cancer Centers participating in NCI-funded clinical trials are eligible to apply for this supplement.

## Not Eligible:

- The most recent CCITLA recipient Cancer Centers (those which received the <u>first</u> payment of a two-year CCITLA supplement in 2018) are <u>not eligible</u> to submit an application in response to this announcement.
- Cancer Centers which will enter an extension year during the fiscal year in which
  this award will be made (FY 2019) are <u>not eligible</u> to submit an application in
  response to this announcement since new administrative supplements cannot be
  paid to grants in an extension year.

### **Eligibility Criteria for Clinical Investigator Candidates**

## All criteria must be met at the time of the application submission deadline (December 7, 2018) to be considered for the award.

- The candidate must be one of the following:
  - Physician (e.g., M.D., D.O.), board certified or have equivalent training and qualifications in specialty area, e.g., medical oncology, radiation oncology, surgical oncology, gynecologic oncology, or equivalent
  - Oncology nurse or clinical psychologist (or similarly qualified clinician) with a doctoral degree
- The candidate must currently be practicing in the oncology clinical setting.
- The start date of the candidate's initial academic appointment following his/her oncology fellowship must be at least 3 years but no more than 8 years before the application submission deadline of December 7, 2018.
- The candidate must be a full-time faculty member (academic or clinical track) at the <u>assistant or associate professor level</u>, eligible for promotion/tenure. A full professor, or anyone above the associate professor level, regardless of

## tenure status, is not eligible to be nominated.

- The candidate must be engaged in the conduct of NCI-funded cancer clinical trials at an academic medical center and have a record of involvement in cancer center clinical trial-related activities.
- The candidate must have 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.
- The candidate must be a United States (US) citizen or noncitizen national of the US possessing a US passport that delineates and certifies status as a national but not a citizen of the US or have been lawfully admitted for permanent residence and possess a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status.
- Candidate cannot have received the CCITLA previously (applies to the candidate only, not to the Cancer Center).
- The candidate may **not currently be or previously have been**:
  - A Principal Investigator (PI) of a National Institutes of Health (NIH) peerreviewed research grant of at least \$125,000 in direct costs per year for a minimum of 3 years, with the exception of mentored career development awards or awards where the PI is required to be mentored by another investigator.
    - Individuals who are currently supported by NIH Mentored Career Development (K) Awards are eligible to be nominated for the CCITLA if the support period for the K grant will end by the date when the CCITLA award will be made (approximately March 2019 for Centers with annual P30 CCSG start dates in December through March; for Centers with P30 CCSG start dates in April September, the CCITLA is awarded on the start date). Since the CCITLA is an administrative supplement and not a research grant, it cannot replace effort on a K award (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-065.html).
  - A project leader or co-leader on a NIH competing multi-component research or center grant or cooperative agreement within a P or U series grant (e.g., P01 Program Project Grant, U01 or U19 Research Program Cooperative Agreement, P50 Specialized Center Grant).
  - A Principal Investigator of a peer-reviewed research grant of at least \$125,000 in direct costs per year for a minimum of 3 years from any of the organizations listed in the Organizations with Peer Review Funding Systems at:
    - https://cancercenters.cancer.gov/PoliciesResources/PoliciesResources

 Recipients of ASCO Career Development Awards or mentored career development awards/grants from other organizations ARE eligible and may be nominated for this award.

Questions about eligibility should be directed to the NCI CCCT CCITLA program at NCICCITLA@mail.nih.gov.

## **Tips for Applicants**

- The application should clearly show that the candidate is involved in NCI-funded clinical trials.
- The application should highlight how this award would permit the candidate to expand current activities and/or develop/engage in new activities related to promoting successful clinical research.
- The application should address the review criteria in the announcement.

## Application (please include the following in the application in the order listed):

1. Cover Letter (1 page) signed by the PI of the P30 CCSG:

A cover letter, signed by the PI of the P30 CCSG, must accompany each application and should **only** include:

- the title of this funding opportunity
- that the center is applying for this administrative supplement
- the name and email address of the candidate and of the administrative official for the application
- the candidate's academic appointment
- the start date of the candidate's initial academic appointment following completion of his/her oncology fellowship
- a statement verifying that the candidate meets all eligibility criteria of the award
- the process used to select the candidate

The Cancer Center Director's letter of support should be included with the other letters of support for the application and not as part of the cover letter.

#### 2. Body of the Application:

The application should include (in the order listed):

1) **Face page:** The standard face page of the PHS 398 (http://grants.nih.gov/grants/funding/phs398/phs398.html).

- Biographical Sketch: A biographical sketch of the candidate. The Biographical Sketch Format Page is available at <a href="http://grants.nih.gov/grants/forms/biosketch.htm">http://grants.nih.gov/grants/forms/biosketch.htm</a>.
  - In Section D. Research Support, list all ongoing, completed and pending research projects (Federally or non-Federally-supported), including the grant #, name of the grant PI, start and end dates of support, funding amount of the grant, title of the grant, goal of the study, and the role of the CCITLA candidate in the project (e.g., Principal Investigator/co-Principal Investigator, co-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) Clinical Trials Table (trials which opened during December 1, 2015 November 30, 2018 and which are currently active, closed but not published, approved or under review): Please refer to Appendix A. Instructions and Template for Clinical Trials Table.
- 4) **Qualifications and Career Plan:** Please address the following (no longer than 6 pages):
  - a. **Training:** Describe specific aspects of the candidate's training which support a clinical team leadership role in oncology clinical trials.
  - b. **Involvement in NCI-Funded Clinical Trials:** What role does/has the candidate played in the development of NCI-funded interventional trials at the cancer center? Describe the candidate's current and past involvement in NCI-funded clinical trials.
  - c. Clinical Trial-Related Activities: Describe the candidate's current and past involvement and any leadership roles in clinical research committees/offices/activities (e.g., clinical trials office, Institutional Review Board (IRB), Data Safety Monitoring Board (DSMB), Protocol Review and Monitoring Committee, Scientific Review Committee, National Clinical Trials Network (NCTN), NCI Community Oncology Research Program (NCORP), NCI Experimental Therapeutics Clinical Trials Network (ETCTN), NCI Cancer Immunotherapy Trials Network (CITN)).
  - d. **Mentoring:** Describe the candidate's current and past mentoring of trainees, junior investigators, students, etc. in support of clinical trial activities.
  - e. Collaborative Team Leadership: How does the candidate serve as a critical supporter and promoter of the overall clinical research mission at his or her institution? Does the candidate's involvement and influence in clinical trials cross disease sites, modalities, or departments? Describe how the candidate works across the institution, with individuals at other

institutions and with outside organizations on clinical trials and clinical trialrelated activities and initiatives.

- f. **Career Plan:** Describe the candidate's plans for a career in academic clinical research and how the institution is supporting the candidate in this plan.
- 5) Planned Activities (no longer than 2 pages):
  - a. **Planned Activities:** An outline and description of activities planned under this award, **including a timeline**.
  - b. Describe how the activities planned under this award build upon the experience and leadership of the candidate beyond merely a continuation of the regular activities.
  - c. Describe how the candidate's regular workload will be adjusted to allow for sufficient dedicated time for the proposed CCITLA activities.

The CCITLA can support multiple projects/activities as time, effort, and resources allow. 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 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, Scientific Review Committee).
- Resolving activation or accrual issues for a trial at the awardee's institution.
- 6) Budget: A budget entered on Form Pages 4 and 5 of PHS 398 (<a href="http://grants.nih.gov/grants/funding/phs398/phs398.html">http://grants.nih.gov/grants/funding/phs398/phs398.html</a>) 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.

- 7) Checklist: The Checklist Form Page of the PHS 398 (http://grants.nih.gov/grants/funding/phs398/phs398.html).
- 8) Letters of Support: Three signed letters of support on behalf of an individual's application must be submitted with the application. The letters should be appended to the application after the PHS 398 Checklist in the PDF of the application.
  - One of the letters of support must be provided by the Cancer Center Director and should be appended to the application with the other letters of support, rather than included in the cover letter.
  - At least one of the letters of support should be an institutional support letter from the Department Chair or appropriate institutional official that indicates:
    - A description of the academic status of the applicant and any additional support provided by the institution.
    - A clear level of commitment by the institution to developing the candidate's career as an academic clinical investigator.
    - The extent to which the candidate will have dedicated time for activities proposed in the application. This letter must demonstrate a commitment to allow at least 15% (1.8 calendar months) effort for activities proposed in the application
    - How the institution intends to continue to provide or augment its support for the candidate's clinical research efforts beyond the award performance period.

## 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:

- title of this funding opportunity
- intent to apply for this administrative supplement
- name of the Cancer Center and Cancer Center Director (PI of the P30 CCSG)
- not required, but please include if known:
  - o the name and email address of the Candidate
  - the names and institutional affiliations of the two individuals other than the Cancer Center Director who will provide letters of support for the application.

The letter of Intent should be provided by e-mail no later than November 19, 2018 to:

CCITLA Program, Coordinating Center for Clinical Trials National Cancer Institute NCICCITLA@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 and Application

Applications are due no later than 5:00 PM local time of applicant organization on December 7, 2018.

Email an electronic copy of the application in PDF format, including the cover letter and letters of support, to <u>both</u> contacts listed below.

CCITLA Program
Coordinating Center for Clinical Trials
National Cancer Institute
NCICCITLA@mail.nih.gov

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

**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 Support 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 Coordinating Center for Clinical Trials (CCCT) 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."

#### **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.

## **Training**

• Does the candidate have formal training and experience strongly supporting a clinical team leadership role in oncology research?

#### Involvement in NCI-funded clinical trials

To what extent has the candidate participated currently and/or in the past in NCI-funded 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 NCI-designated Cancer Centers?

#### **Experience and clinical trial-related activities**

- To what extent is the candidate currently involved in and/or does the candidate have past experience in clinical-trial related activities (e.g., 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), NCI Experimental Therapeutics Clinical Trials Network (ETCTN), NCI Cancer Immunotherapy Trials Network (CITN), clinical trials not funded by the NCI)?
- To what extent does the candidate mentor or guide trainees, junior investigators, students, etc. in support of clinical trial activities?

#### Collaborative team leadership

 To what extent does the candidate serve as a critical supporter and promoter of the overall clinical research mission at his or her institution?

- Does the candidate's involvement and influence in clinical trials cross disease sites, modalities, or departments?
- To what extent does the candidate work across the institution in clinical trials and clinical trial-related activities?
- To what extent does the candidate work with individuals at other institutions and with outside organizations on clinical trials and clinical trial-related activities?

## Candidate's planned activities

- Are the activities proposed new for the candidate and/or an **expansion** of regular activities rather than a continuation of regular activities?
- Do the activities planned under this award build upon the experience and leadership of the candidate beyond merely a continuation of the regular activities?
- Will this award allow the candidate to develop/engage in new activities related to clinical trials at his/her institution that would not likely happen without this award?
- To what extent do the activities proposed in the application promote and/or enhance clinical trial-related activities and a successful clinical research culture at the candidate's institution?
- Does the application indicate appropriate commitment of time and effort for the proposed activities?
- Will the candidate be able to devote sufficient time to both the CCITLA activities and non-CCITLA activities/duties/responsibilities or will the candidate be overcommitted?
- To what extent do the activities proposed in the application promote retention of the candidate in an academic clinical research career?

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

- Is there clear commitment of the institution to relieve the candidate of sufficient duties to allow at least 15% (1.8 calendar months) effort 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?

 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?

#### **NCI Contact Information**

For programmatic questions concerning this supplement, contact the NCI CCITLA program in the Coordinating Center for Clinical Trials (<a href="NCI CITLA@mail.nih.gov">NCI CITLA@mail.nih.gov</a>) or 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.

## Appendix A. Instructions and Template for Clinical Trials Table

Using the template in this Appendix, list all clinical trials which the candidate has had a role in which **opened during December 1, 2015 – November 30, 2018 and which are currently active, closed but not published, approved or under review.** Only interventional trials should be listed in this table. Use legal size paper for the table if needed.

Sort the trials by Study Source:

- National: NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks
- Externally Peer-Reviewed: R01s, SPORES, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or an organization listed in the Organizations with Peer Review Funding Systems at: https://cancercenters.cancer.gov/PoliciesResources/PoliciesResources
- Institutional: In-house clinical research studies authored or co-authored by Cancer Center investigators and undergoing scientific peer-review solely by the Protocol Review and Monitoring System of the Cancer Center. The Cancer Center investigator has primary responsibility for conceptualizing, designing and implementing the clinical research study and reporting results.
- **Industrial**: The design and implementation of these clinical research studies is controlled by the pharmaceutical company or other institution.

**Specific Funding Source:** The specific name of the financial sponsor(s) for the clinical trial. For institutionally sponsored trials, list the name of the applicable funding agencies.

**Anatomic Site:** The anatomic cancer site(s) (*i.e.* breast, ovary) the clinical trial focuses on. If the trial is broadly applicable to several anatomic sites, enter the term "multiple" in this column.

**NCT ID:** Provide the unique ID assigned to the trial by the National Clinical Trial program (ClinicalTrials.gov) for trials that have been submitted to ClinicalTrials.gov Protocol Registration System (PRS) previously. The ClinicalTrials.gov ID appears as "NCT" followed by 8 numeric characters (such as NCT12345678). If not applicable, enter "N/A" in this column.

**Other ID(s):** Provide the unique identifier for this trial. Where available, list the common protocol number that the trial is known under nationally, if one exists. For other trials that do not have a common protocol number that the trial is known under nationally, use an internal protocol identification or IRB number.

**Candidate's Role:** The role of the CCITLA candidate in the trial (e.g., 'Overall PI', 'Overall Co-PI', 'Site PI', 'Associate Investigator', etc.)

**Overall PI:** The last name and first name of the overall PI for this Clinical Trial.

Date Open: Overall (activation): The official start date of the trial determined by 1) the

date of activation noted in an official clinical trial activation announcement or 2) date of first patient accrual if the trial in question did not have a formal activation announcement. For multi-Institutional trials that your Center participates in but did not initiate, leave "Date Open: Overall" column empty if not known.

**Date Open: Site (activation):** The date the trial opened at your Center.

**Date Closed**: The date the trial closed to accrual at your Center. This does not include patient follow-up. If the trial is still open, leave this field blank.

**Status (as of November 30, 2018):** Active, Approved, Under Review, Closed - Not Yet Published, Enrolling by Invitation, Temporarily Closed to Accrual, Temporarily Closed to Accrual and Intervention, or Temporarily Not Available

**Phase:** For Interventional trials acceptable phases include: pilot, feasibility, 0, I, II, III, IV, or combinations such as I/II. For trials without phases, indicate "N/A."

**Official Title:** Official name of the protocol provided by the trial PI or sponsor (Limit: 8000 characters or fewer).

**Multi-Inst Trial:** Indicate if the trial is multi-institutional by inserting 'Yes' or 'No' in the "Multi-inst trial" column.

Multi-Institutional Clinical Trial: Clinical trial that recruits participants from two or more geographically distinct enrollment Institutions not affiliated with your cancer center (e.g., other NCI-designated Cancer Centers or other research institutions). The Institutions are usually distinct in other characteristics (e.g., demographic, socioeconomic, or clinical).

#### **Total Targeted Accrual:**

- Entire Trial: For both single-institution and multi-institutional trials initiated at your Center, indicate the total number of participants needed for the entire trial. For multi-Institutional trials that your Center participates in but did not initiate, leave "Entire Trial" column empty if not known. Do not submit a targeted range, such as "10 100."
- Your Center: For single-institution and multi-institutional trials initiated at your Center, indicate the total number of participants your Center is expected to accrue for the study. For single-institution trials the "Total Accrual for Your Center" and the "Total Targeted Accrual Entire Trial" numbers will be the same. Do not submit a targeted range, such as "10 100."

**Cancer Center Accrual:** List the number of participants enrolled in the clinical trial at your Cancer Center, including formal Consortium Partners.

- **12 Months:** Provide the number of participants accrued to this clinical trial during the last 12 months.
- **To Date**: Provide the number of participants accrued to this clinical trial since the trial was opened.

#### TEMPLATE FOR CLINICAL TRIALS TABLE

**CCITLA Clinical Trials Table** 

Candidate for Cancer Clinical Investigator Team Leadership Award (CCITLA): [Name of Candidate]

[Name of] Cancer Center Reporting Period: 12/01/2015 – 11/30/2018

NATIONAL Trials													Total		Cano	
														Targeted		ter
													Acc	rual	Accr	ual
Specific	Anatomic	NCT ID	Other ID(s)	Candi-	Overall	Date	Date	Date	Status	Phase	Official Title	Multi-	Entire	Your	12	To
Funding	Site			date's	PI	Open:	Open:	Closed:				Inst	Trial	Center	months	Date
Source				Role		Overall		Site				Trial?				
																1
	1															
																<b>—</b>
																1
																Ì

ADD ADDITIONAL ROWS AS NEEDED

EXTERNALLY PEER-REVIEWED Trials													Total Targeted		Cano	cer
															Cent	ter
										Accrual		Accr	ual			
Specific	Anatomic	NCT ID	Other ID(s)	Candi-	Overall	Date	Date	Date	Status	Phase	Official Title	Multi-	Entire	Your	12	To
Funding	Site			date's	PI	Open:	Open:	<b>Closed:</b>				Inst	Trial	Center	months	Date
Source				Role		Overall	Site	Site				Trial?				

ADD ADDITIONAL ROWS AS NEEDED

CONTINUED ON NEXT PAGE

**CCITLA Clinical Trials Table** 

Candidate for Cancer Clinical Investigator Team Leadership Award (CCITLA): [Name of Candidate]

[Name of] Cancer Center

**Reporting Period: 12/01/2015 – 11/30/2018** 

INSTITUTIONAL Trials													Total Targeted		Cancer	
															Center	
													Acc	rual	Accr	ual
Specific	Anatomic	NCT ID	Other ID(s)	Candi-	Overall	Date	Date	Date	Status	Phase	Official Title	Multi-	Entire	Your	12	To
Funding	Site			date's	PI	Open:	Open:	Closed:				Inst	Trial	Center	months	Date
Source				Role		Overall	Site	Site				Trial?				
																1
																1
																1

ADD ADDITIONAL ROWS AS NEEDED

INDUSTI	INDUSTRIAL Trials														Cano Cent Accr	ter
Specific Funding	Anatomic Site	NCT ID	Other ID(s)	date's	Overall PI		-	Date Closed:		Phase	Official Title	Multi- Inst	Entire		12 months	To
Source				Role		Overall	Site	Site				Trial?				

ADD ADDITIONAL ROWS AS NEEDED