

The NCCN Foundation Young Investigator Award Program

2013 Request for Proposals

The NCCN Foundation invites proposals from young investigators with innovative ideas and an interest in the development and application of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]). Research projects may focus on guideline application in decision-making and formation of policies related to access to, availability and utilization of drugs, biologics, devices, procedures and techniques in cancer care decision-making may be focused on clinical processes, economic issues, and policy processes, with an emphasis on public and private coverage policies.

The NCCN Foundation

The National Comprehensive Cancer Network (NCCN), a not-for-profit alliance of 21 of the world's leading cancer centers, is dedicated to improving the quality, effectiveness, and efficiency of care provided to cancer patients. Since its inception, NCCN has accomplished this primarily through its leadership and expertise in developing the Clinical Practice Guidelines and its extensive program of professional education and training. The NCCN Foundation, founded in 2010, seeks to extend and enhance that mission by training the next generation of clinical experts and supporting high quality research and clinical practice related to health services and policy with an emphasis on use of guidelines in quality monitoring and improvement, patient education, and influence on coverage.

The Young Investigator Awards

The NCCN Foundation Young Investigator Awards (YIA) represent an ongoing program to provide two-year grants of \$75,000, per annum, for direct research expenses to promising young investigators across a broad range of oncology specialties and areas of interest. The awards may include funds up to \$16,000 for data collection and research support (e.g., biostatistics) and \$3,000 for IRB review and continuing review. Non-research related expenses will be covered to a maximum of 8% within the overall budget. A separate administrative allowance, in addition to the \$75,000 per annum award, may be provided for the expenses of participating in the annual NCCN meeting during the second year of the award. The award is open to physicians, scientists, and nurses working in an oncology laboratory, clinical research or clinical setting, or cancer control program in one of the NCCN's 21-member institutions, who (1) have a first full-time appointment as an Assistant Professor, Instructor, or an equivalent level, or (2) are MD's, PhD's or, for oncology nurses, have an appropriate-level advanced degree. The award may be used to fund salary and benefits of the grant recipient, postdoctoral or clinical research fellows and/or research assistants; data collection and entry; patient costs; analysis; computer costs; necessary purchased services, e.g., surveys; and supplies.

Each NCCN Member Institution may submit up to two applications and is asked to consider one application from each of the two categories of investigation summarized below:

- (a) research pertaining to the NCCN Guidelines[®] :

- uptake of the guidelines at the host institution
- effects of using the guidelines on patient care
- use of patient versions of the guidelines in patient education efforts
- implementation of guidelines in the electronic health record
- impact of supportive care guidelines application on quality of life
- extension of the guidelines to survivorship services
- impact on access to and availability of drugs, biologics, devices, procedures and techniques
- applicability of guideline processes to comparative effectiveness, analysis, etc.
- impact on public policy, with an emphasis on coverage polices.

(b) new prevention, detection or treatment approaches for cancer and its translation into clinical care through evaluative information products or policies. This category does not need to pertain to the NCCN Guidelines but may do so.

Clinical Practice Guidelines Leadership Development

From its inception, the NCCN's signature achievement has been the development of comprehensive clinical practice guidelines for cancer treatment. These guidelines, which now cover 98% of all cancer patients, and common supportive care issues, are recognized as the gold standard for cancer treatment nationally and internationally. The guidelines result from a remarkable process which brings together the leading experts from the NCCN Member Institutions. Working together, site specific panels create and maintain state of the art treatment recommendations using an algorithm that addresses every step in the diagnosis and treatment process across the continuum of care. A primary focus of the NCCN Foundation Young Investigator Awards will be to identify and fund top clinicians, scientists and nurses in the early stages of their careers interested in participating and contributing to the development of clinical practice guidelines through research and elucidating how the guidelines are implemented in practice and public policy. Successful candidates will identify and work closely with an appropriate institutional mentor conversant with the guidelines, health policy, and health quality initiatives. Additionally, institutions will have an institutional review process in place for the guidelines and provide opportunities for candidates to be fully involved in this process. Initial YIA grant applications should focus on high incidence, high impact disease sites, including but not limited to breast, lung, colorectal, prostate and hematologic malignancies, as well as important supportive care areas that affect patients with these diseases. Candidates will be expected to develop a timeline for their two-year Young Investigator Awards, culminating in the presentation of select studies with final data and results at the NCCN Annual Conference held each March in Hollywood, Florida.

Research Projects Focusing on Health Policy, Patient Education, and Quality of Life

The Foundation recognizes the growing need for evidence-based health services research in the areas of health policy, quality of life for cancer patients, and patient education. These include concerns for how clinical and policy processes use and integrate data and the impact of available options for the optimal management of cancer patients. The NCCN Foundation Young Investigator Awards provide opportunities to address critical needs in these areas, as well as to apply a perspective to the use of new diagnostics and molecular markers in clinical management. A hallmark of NCCN's programs has been

strong attention to excellent data collection, analysis and outcomes measures. Successful YIA applications will be expected to bring this same high level of rigor to their research and clinical practice programs.

Number of Awards in 2013

For the grant cycle beginning in 2013, the NCCN Foundation anticipates making four (4) Young Investigator Awards. Three YIA's will be open to all cancer disease sites and should reflect the applicant's primary career and research interests. A fourth YIA will be considered and reviewed on all relevant aspects of personalized medicine in oncology.

Important Dates:

- Application Deadline: March 21, 2013
- Committee Review: April 22, 2013
- Start of the Grant Term/Award Letters: May 1, 2013.

Eligibility Requirements:

Applicants must have:

- Medical degree--MD, DO or international equivalent or
- Scientific degree--PhD or international equivalent or
- Nursing degree--Masters and above or international equivalent
- Primary affiliation/work site must be in a NCCN Member Institution
- Candidates must be in their first full-time appointment in an NCCN institution
- Candidates must not have other funding that duplicates the focus and purpose of this award
- Mentor in the proposed research field, fully conversant in the clinical practice guidelines
- Institutional commitment, including demonstration of an active review process for the guidelines

The NCCN Foundation and its Grants Selection Review Committee reserve the right to evaluate and determine applicants' eligibility based on the information and justifications included in the application materials.

Application Process

All applications must be submitted in accordance with the requirements and instructions of this Request for Proposal (RFP). All applications must be in English and submitted on-line via a secured website.

Each NCCN Member Institution may nominate and submit the application proposals on behalf of two (2) candidates per institution. Access to a secured website will be provided to each candidate as he/she is identified. Candidates will register on the secured website and have direct access to the proposal submission form and an NCCN Foundation YIA Budget template through the website's "Resource Center." They will be required to upload additional documents for this RFP through the website's "Essential Documents."

Proposals are required to be submitted by the institution's Office of Sponsored Research and include a letter of support from the governing groups of the institution verifying 1) the proposal has Department Chair/Division approval, 2) institutional budgetary review and approval, 3) the priority status of the research should funding be approved, and 4) the study includes data collection and research support (e.g., biostatistics).

Through the secured website, proposals will provide concise documentation of the research plan. The proposal is expected to contain sufficient information to allow the reviewers to fully assess the scientific rigor of the proposed study. A full protocol may be submitted as an attachment to a proposal.

The full application must include the following components:

- 1. Contact information*** (YIA candidates will enter this information when registering on the secured website, this will automatically populate on the proposal submission form.)
- 2. Project information*** (YIA candidates are asked to provide all applicable information requested on the proposal submission form on the secured website.)
- 3. Applicant's biosketch** (to be uploaded on the secured website through "Essential Documents.")
- 4. Research plan** (Information to be provided in proposal submission form.)
- 5. Cited references** (Information to be provided in proposal submission form.)
- 6. Budget and justification** (to be uploaded on the secured website through "Essential Documents." *NB:* YIA candidates should use the NCCN Foundation YIA Budget template provided on the secured website's "Resource Center.")
- 7. Mentor's contact information and biosketch** (to be uploaded on the secured website through "Essential Documents.")
- 8. Mentor's letter of support** (to be uploaded on the secured website through "Essential Documents.")
- 9. Institutional letter of support** from center director, dean or department head (to be uploaded on the secured website through "Essential Documents.")
- 10. Signed Institutional Approval Face Sheet** (to be uploaded on the secured website through "Essential Documents.")

Required Information by Section

1. Contact Information

- Name
- Address, phone number, email address
- Title
- Institution
- Degree

2. Project Information *YIA Nominees are asked to fill in all required project information on the proposal submission form including:

- Project Title
- Investigators, including a statistician and institutional affiliations
- Abstract (Include in Study Summary in proposal submission)

- Hypothesis/objectives
- Research design
- Study population
 - Stage
 - Major inclusions/exclusions
- Treatment plan
- Endpoints/Statistical analysis
- Feasibility
 - Estimated time of completion/monthly accrual
 - Previous experience
 - Collaborators, if any, and their experience, including affiliates
- Lay summary (Include in Study Summary in proposal submission)
- Assurances for use of human subjects and/or animal subjects in the proposal

3. Applicant Biosketch: Applicants may use their NIH biosketch if available. Not to exceed two pages.

4. Cited References: A list of cited references should be included in the proposal submission form.

5. Budget and Budget Justification: The award funds will be directed to the sponsoring institution and should be used toward salary support, supplies, data collection, patient costs, travel, etc., necessary for the research project. Awards funds may not be applied to patient care costs that are reimbursable by third party payers. The budget guidelines are as follows:

- Breakdown by major cost categories.
 - Total award: The annual award amount is \$75,000. The suggested distribution that follows may be adjusted, provided that all allocation requirements are met:
 - Research support: \$50,000
 - Data collection and analysis: \$16,000
 - IRB fees up to \$3,000
 - Non-research related expenses (not exceeding 8% of the award amount (\$6,000 per annum)¹
- Justification of major costs with enough detail to demonstrate how funding for major elements in the study will be allocated.
- For combined clinical and correlative studies, separate budgets for each component should be submitted.
- Separate budgets for each of the two years of the Award.

6. Mentors Contact Information and Biosketch: Mentors may use their NIH biosketch if they have one available. The biosketch should not exceed four pages and include contact information.

7. Mentor's Letter of Support: This should include the following:

¹ These expenses must be expressed as direct expenditures. Funders of this Program have specific clauses in their agreements that do not permit payment for "indirect costs."

- Confirmation that the applicant is a full time employee or faculty member of the member institution
- A critical review of the applicant and the research proposal
- Current and/or anticipated role the applicant holds at the institution
- Assurance that the sponsoring institution will provide adequate facilities and support for the proposed work, including gateways to participate in the relevant committees dealing with guideline review and application
- Intended structure of the mentor/investigator interaction during the proposed project.

8. Institutional Letter of Support:

- A letter from the cancer center director, department head or dean at the sponsoring institution must be provided and include a statement that institutional support will enable the applicant to perform the proposed research and clinical practice guideline development.

9. Institutional Approval:

- An authorized official representing the institution must approve the completed application-- both the proposal and the budget--before submission. This official is normally from the institution's Office of Sponsored Research. The Institutional Approval Face Sheet must be signed and uploaded before the submission will be considered complete.

Selection Process

The NCCN Foundation Grants Selection Review Committee will select recipients for Young Investigator Awards based on the following criteria:

- Significance and originality of the proposed study
- Appropriateness and adequacy of the proposed methodology
- Focus on issues related to use of guidelines in health services research, patient education, survivorship, and quality of life that impact the ability to deliver care to patients
- Qualifications and experience of the applicant
- Availability of institutional resources to support the project
- Quality of the mentor and interaction between mentor and applicant for the project.

Administration:

The NCCN Foundation will support the review, selection and granting of the Young Investigator Awards in consultation with the NCCN Oncology Research Program (ORP). Both ORP and NIH standards will be used by the YIA Grants Selection Review Committee to review and score proposals received in response to this RFP. Review Committee members will be drawn from NCCN Member Institutions and have expertise in the broad spectrum of clinical and nursing research areas for the Young Investigator Awards. Their expertise will be supplemented by NCCN senior staff with background in guideline development, outcomes research, and biostatistics. Individual Review Committee members will recuse themselves from reviewing applications for their own institutions.

Questions about this RFP, from either applicants or their institutions, should be emailed to: FoundationProposals@nccnfoundation.org Replies will be sent within 24-48 hours.