To:UPMC Hillman Cancer Center ResearchersFrom:Sid Kar, PhDDate:March 6, 2020	
Titles:	Six new CCSG Supplement RFAs from the NCI: (1) HPV vaccine, (2) COE activities, (3) Financial hardship during cancer treatment, (4) Interdisciplinary research on cancer and aging, (5) Patterns of cannabis use among cancer patients, and (6) National Childhood Cancer Registry development
Deadline:	<ul> <li>Hillman Cancer Center Internal Deadline: March 20, 2020</li> <li>UPMC Hillman Cancer Center has been invited to submit <u>one application</u> for each of the above-referenced awards. If you would like to be considered, please email your biosketch and a <u>two-page pre-proposal</u> to Dr. Sid Kar (<u>kars@upmc.edu</u>). Since there are six RFAs, please make sure to <u>include the specific supplement title/topic in your pre-proposal document, file name, and email</u>. One proposal for each award will be selected to apply after internal review.</li> <li>NCI Deadline: May 4, 2020</li> </ul>
Description:	See attached RFAs.
Award Information:	Duration and budget may be different for each award. Please refer to the attached RFAs.
Eligibility:	Open to Cancer Center members. Applications are supplements to the NCI Cancer Center Support Grant.
Applications and Instructions:	See attached RFAs
For More Information:	Contact Dr. Sid Kar ( <u>kars@upmc.edu</u> ).

# Administrative Supplements for the NCI P30 Cancer Center Support Grants for new interdisciplinary research on cancer and aging

# Background

Contemporary improvements in early detection and diagnosis, cancer treatment, and the implementation of populationbased cancer prevention and control strategies have contributed to a sustained decline in overall cancer mortality rates. Although this trend is promising, challenges at the nexus of cancer and aging are, in turn, becoming more prominent. Older adults (age 65 years and older) are the largest growing segment of the U.S. population, and aging into older adulthood is associated disproportionally with the incidence of common cancers. As survival rates for some pediatric, adolescent and young adult (AYA), and common adult-onset cancers improve, the number of cancer survivors, particularly among older adults, and the number living with treatment-related consequences will continue to increase. Emerging evidence suggests some cancers and cancer treatments change the hallmarks of aging, shift aging trajectories, influence aging-associated outcomes like gait speed, frailty, and functional independence, and increase risks for multimorbidity and subsequent malignancies.

This shifting survivorship landscape has profound implications for cancer care delivery, coordination and transitions, and the cancer research enterprise. Despite the relationship between advancing age and cancer risk, older adults are underrepresented in observational and intervention cancer prevention and control studies, relative to other age groups. There are opportunities to expand eligibility criteria, design intervention studies explicitly for older adults, and include - as scientifically justified - aging biomarkers, assessments (e.g., geriatric assessment) and endpoints relevant to the inherent heterogeneity in biologic, phenotypic, and functional aging. Moreover, even along the pre-clinical to translational research continuum, opportunities exist for the development and use of age/aging-relevant and clinically-informative animal models of human cancers and treatment-related late effects.

The <u>NCI Annual Plan & Budget Proposal for Fiscal Year 2020</u> highlighted the need to increase understanding of the role of aging in cancer. The convergence of demographic, epidemiologic, and societal trends makes primary through quarternary cancer prevention during older adulthood a public health imperative. A lifespan approach to the elimination or reduction of cancer risk associated with obesity, tobacco use, and physical inactivity is critical for the primary prevention of cancers and other chronic conditions that contribute substantial public health burden during mid-life and older adulthood. Surveillance methods are needed to track aging-relevant factors associated with cancer burden (e.g., multiple chronic conditions, polypharmacy, short- and long-term adverse effects, financial toxicity, residential stability & institutional care transitions (e.g., nursing homes, hospice) and behavioral and social exposures). As pediatric and AYA cancer survivors age chronologically and biologically and experience adverse physical, psychosocial, and behavioral outcomes, interventions to prevent, ameliorate or rehabilitate aging-related consequences of cancer and its treatments are a priority. Strategic investments in aging research will contribute to population health by preserving or promoting healthspan and ensuring equitable access to and benefit from advances in cancer prevention, control, and population-science.

# **Purpose and Goals**

The National Cancer Institute (NCI), Division of Cancer Control and Population Sciences (DCCPS), announces the opportunity for supplemental funding to provide support for the development of an interdisciplinary research infrastructure focused explicitly on aging/geroscience and cancer prevention, control, or population science. NCI-designated Cancer Centers have the potential to build sustainable interdisciplinary research infrastructures to address critical cancer and aging research questions or catchment area needs. The short-term goal of this one-year supplement is to shape the development of an aging focus in cancer prevention, control, or population science programs.

Through this opportunity, short-term support can be requested to:

- Catalyze new research programs
- Convene and coordinate new transdisciplinary research groups
- Facilitate new collaborations with various sources of aging expertise (e.g., academic departments of gerontology, aging research foundations, NIH-funded aging researchers, NIA Centers)
- Identify aging-related Center research, clinical, and community outreach and engagement priorities through rigorous mixed-methods approaches

- Use novel methods (e.g., ideas labs, scoping sessions, virtual workshops) to foster partnerships, support team science, engage aging scientists, clinicians, and other aging-related expertise, and build new research, clinical, and community outreach communities
- Support strategic planning and agenda-setting
- Augment cancer-focused research capacity by consulting with faculty conducting significant, timely, innovative, visionary, and highly meritorious aging research

The long-term goal is to advance cancer prevention, control, and population science by leveraging knowledge about the nature of aging (including the biology of aging) and the aging process.

## **Eligibility and Budget**

- This opportunity is open to all P30 Cancer Center Support Grants.
- Only one supplement request per center will be considered.
- Supplement requests may not exceed \$150,000 total costs, and the project period is for one year.
- Cancer Centers whose P30 Cancer Center Support Grant will be in an extension at the time of award are not eligible.
- It is anticipated that awards for this supplement opportunity will be made in September 2020.

# **Application Submission Format**

Applications should be submitted as a signed, scanned PDF to Mary O'Connell (<u>oconnellm@mail.nih.gov</u>) and Stacey Vandor (<u>stacey.vandor@nih.gov</u>) no later than COB May 4, 2020.

Email confirmation of application receipt from Stacey Vandor must be obtained to be officially considered and evaluated.

Requests must include the following:

- The Standard PHS 398 Face Page
- A detailed budget and budget justification
- NIH biographical sketches for key personnel proposed in the supplement
- Summary of the project (not to exceed 5 pages) (references are excluded from the 5-page limit; no appendices, please)

The 5-page summary must:

- Describe how the integration of aging/geroscience can strengthen the Center's cancer prevention, control, or population science research focus; enhance transdisciplinary collaboration and coordination; and, engage communities within the catchment area to decrease cancer burden.
- Describe the proposed infrastructure development activities and the interdisciplinary nature of the personnel involved.
- Explain how the proposed interdisciplinary infrastructure development activities will advance the Center's capacity to address specific cancer and aging research questions or aging-relevant catchment areas needs.
- Describe why the proposed infrastructure development activities cannot be achieved through existing programs, structures, and collaborations within the Center.
- Clearly describe a one-year plan, with a timetable and milestones, to sustain support for the cultivation and submission of competitively funded research grants and contracts that address critical interdisciplinary cancer and aging research questions or aging-relevant catchment areas needs.
- Describe the qualifications of the individual(s) who will conduct the work. Briefly elaborate on each person's CV in the narrative response.

# **NCI Evaluation of Supplement Requests**

Administrative supplements do not receive peer review. Instead, NCI staff with expertise in cancer prevention and control will evaluate supplement requests to determine overall merit. Proposals will be reviewed for quality and for responsiveness to application criteria outlined in the requirements for the five-page summary described above.

#### **Reporting Requirements**

As part of the progress report for the parent Cancer Center Support Grant, information must be included on what has been accomplished via the administrative supplement as well as the Cancer Center's plans to sustain support for the cultivation and submission of competitively funded research grants and contracts that address critical interdisciplinary cancer and aging research questions, or aging-relevant catchment areas needs.

### **Pre-Submission Informational Webinar:**

An informational webinar will be held as noted below:

Time: Wednesday, March 18, 2020, 12:00 PM Eastern Time (US and Canada)

#### The registration link is as follows:

https://cbiit.webex.com/cbiit/onstage/g.php?MTID=efd5d082d707e740d9e21c3b1a67209c1

Dial-in information:

Call-in toll number (US/Canada)

1-650-479-3207

Meeting Number/Access Code: 739 299 805

Event password: J2d5pEBZw\$6

#### Questions

For technical inquiries (including eligibility), please contact your cancer center grant administrator or your NCI program director. For inquiries about the scientific objectives and goals of this supplement, please contact Paige Green (paige.green@nih.gov) or Lisa Gallicchio (lisa.gallicchio@nih.gov).

# Administrative Supplements for the NCI P30 Cancer Center Support Grants to determine patterns of cannabis use among cancer patients

### Background

In 2018, 43.5 million people aged 12 years or older in the United States (US) used cannabis (marijuana) in the past year<sup>1</sup>. The legal landscape of medical and recreational cannabis use is rapidly evolving with wide variation in state policies. The available delivery methods of cannabis have also undergone dramatic changes and include edibles, oils, tinctures, topicals, and inhaled forms. Vaping tetrahydrocannabinol (THC), the psychoactive cannabinoid in cannabis, has been implicated in the cause of severe respiratory illness<sup>2</sup>. Consequently, state-based policy changes are taking place at a time when research on the potential beneficial or adverse health effects of cannabis use and the impact on use among cancer patients across a variety of geographic settings remains limited. A survey of cancer patients conducted within a six-week period between 2015 and 2016 in the state of Washington, where medical and recreational cannabis use is legal, found that 24 percent of patients were active users<sup>3</sup>. This is coupled with survey evidence that a majority of US medical oncologists engage in discussions about cannabis use with patients, and almost half recommend it clinically; yet, few feel sufficiently informed to make recommendations regarding its use<sup>4</sup>. Common conditions for which it has been used among cancer patients include anorexia, nausea, and pain. The extent of use, the perceived and real benefits and risks of use, potential interactions with cancer treatment and other medications, and impact on comorbid conditions are uncertain. Clinicians should be aware of the extent of use in order to assess potential drug-drug interactions, side effects, and contraindications; hence, an understanding of how cancer patients and clinicians engage in discussions about cannabis use is essential. A first step in addressing research gaps regarding cannabis and cancer is to understand the patterns and extent of cannabis use among cancer patients, including those undergoing or having recently completed active treatment.

### **Purpose and Goals**

The National Cancer Institute (NCI), Division of Cancer Control and Population Sciences (DCCPS), announces the opportunity for supplemental funding aimed at NCI-designated cancer centers to conduct surveys in a representative sample of ambulatory cancer patients to better understand patterns of cannabis use. The purpose of this opportunity is to provide resources to support the time and effort of investigators at NCI-designated cancer centers to plan and administer a survey that will include data on the frequency and duration of cannabis use, modes of use, reasons for use, discussion of use with clinical providers, and perceived risks and benefits associated with use among cancer patients undergoing or have recently completed active treatment. Cancer patients should be typical of those seen and treated in the NCI-designated cancer centers' facilities.

A number of annual sources of population-based surveillance data related to cannabis exist; <u>CDC's</u> <u>Behavioral Risk Factor Surveillance System</u> is one source. These surveillance sources may be useful to identify measures that determine frequency of use over a short period of time, mode of use and reasons for use (medical vs non-medical). Additional references and survey instruments can be garnered from a

<sup>&</sup>lt;sup>1</sup> Substance Abuse and Mental Health Services Administration. (2019). *Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health* (HHS Publication No. PEP19-5068, NSDUH Series H-54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <u>https://www.samhsa.gov/data/</u>

<sup>&</sup>lt;sup>2</sup> Blount BC, Karwowski MP, Shields PG, et al. Vitamin E Acetate in bronchoalveolar-lavage fluid associated with EVALI. *N Engl J Med*. 2020; 382:697-705.

<sup>&</sup>lt;sup>3</sup> Pergam SA, Woodfield MD, Lee CM, et al. Cannabis use among patients at a comprehensive cancer center in a state with legalized medicinal and recreational use. *Cancer*. 2017; 123:4488-4497.

<sup>&</sup>lt;sup>4</sup> Braun IM, Wright A, Peteet J, et al. Medical oncologists' beliefs, practices, and knowledge regarding marijuana used therapeutically: A nationally representative survey study. *J Clin Oncol*. 2018; 36:1957-1962.

recent survey of <u>cannabis use among patients at a comprehensive cancer center in a state with legalized</u> <u>medicinal and recreational use</u>.

### **Eligibility and Budget**

- This opportunity is open to all clinical and comprehensive P30 Cancer Center Support Grants.
- Only one supplement request per center will be considered.
- Supplement requests may not exceed \$150,000 total costs, and the project period is for one year.
- Cancer centers whose P30 Cancer Center Support Grant will be in extension at the time the award is made in FY20 are not eligible for this supplement.
- To be considered responsive for supplemental funding, applicants must propose a data collection effort that employs survey research methods and must not rely only on qualitative focus groups, key informant interviews, or analysis of secondary data.
- Funding will support all data collection activities with a goal of approximately 1,000 respondents representative of patients treated at the NCI-designated cancer center facilities and may also support participant incentives to encourage response.
- It is anticipated that awards for this supplement opportunity will be made in September 2020.

### **Application Submission Format**

Applications should be submitted as a signed, scanned PDF to Gary Ellison (<u>ellisong@mail.nih.gov</u>) and Stacey Vandor (<u>stacey.vandor@nih.gov</u>) no later than COB May 4, 2020.

Email confirmation of application receipt from Stacey Vandor must be obtained to be officially considered and evaluated.

Requests must include the following:

- The Standard PHS 398 Face Page
- A detailed budget and budget justification
- NIH biographical sketches for key personnel proposed in the supplement
- Summary of the project (not to exceed 5 pages) (references are excluded from the 5-page limit; no appendices, please)

- Provide an overview of the cancer center's patient population.
- Describe the process by which the survey will be developed and the frame from which the sample will be drawn.
- Provide a complete description of methods used to derive the sample and sample survey design, including survey development, study procedures and items to be collected.
- NCI requires collection of the following core elements related to the use of cannabis:
  - o Current and past use of cannabis
  - Frequency and duration of use
  - Mode of use
  - Therapeutic reasons for use
  - Perception of benefit or risk/harm
  - Discussion of use with clinical providers
  - Recommendations from clinical providers
- Collection of information regarding tumor types and current and past treatment of survey respondents is desirable but not required.
- The survey is expected to include patients covering a diverse population by age, sex, race, and tumor types. Because of the sensitive nature involving the use of cannabis, applicants are strongly encouraged to conduct anonymous surveys.

- Outline a work plan that provides a timeline for development and implementation of the research, including staff involved, staff training and hiring plans, etc. The work plan should include relevant milestones for completing the work within the one-year timeframe of the administrative supplement.
- Describe the qualifications of the individual(s) who will conduct the work. Briefly elaborate on each person's CV in the narrative response.

### **NCI Evaluation of Supplement Requests**

Administrative supplements do not receive peer review. Instead, NCI staff with expertise in cancer prevention and control will evaluate supplement requests to determine overall merit. Proposals will be reviewed for quality and for responsiveness to application criteria outlined in the requirements for the five-page summary described above.

#### **Reporting Requirements**

Centers will be encouraged to consult with NCI in the early stages of their projects in order to identify potential common data elements that will enable comparability across projects. NCI expects that core elements will be standardized across Centers before survey instruments are finalized.

As part of the progress report for the parent cancer center grant, information must be included on what has been accomplished via the administrative supplement (program details such as survey methodology; administration of the survey protocol; progress on timeline tasks; and results describing prevalence and patterns of cannabis use among cancer patients). In addition, relevant challenges and barriers to implementation should be noted. Project leaders should plan to participate in conference calls with NCI staff to discuss sets of core data elements to be collected across all projects. Centers will be expected to report results in peer-reviewed journals and through scientific seminars and national meetings.

### Pre-Submission Informational Webinar:

An informational webinar will be held as noted below:

Time: Wednesday, March 18, 2020, 12:00 PM Eastern Time (US and Canada)

The registration link is as follows: https://cbiit.webex.com/cbiit/onstage/g.php?MTID=efd5d082d707e740d9e21c3b1a67209c1

Dial-in information:

Call-in toll number (US/Canada)

1-650-479-3207

Meeting Number/Access Code: 739 299 805

Event password: J2d5pEBZw\$6

#### Questions

For technical inquiries (including eligibility), please contact your cancer center grant administrator or your NCI program director. For inquiries about the scientific objectives and goals, please contact Gary L. Ellison (ellisong@mail.nih.gov).

# Administrative Supplements for the NCI P30 Cancer Center Support Grants to develop the National Childhood Cancer Registry

# Background

Childhood cancer patients comprise a special and understudied population of cancer patients. Approximately 15,000 childhood cancer patients are diagnosed in the United States annually, compared with the 1.7 million new cancer cases diagnosed each year. Due to their rare nature, it has been challenging to collect substantial and vital information on a large scale to study and understand the needs for this unique population of cancer patients.

The Childhood Cancer Data Initiative (CCDI) symposium hosted by the National Cancer Institute (NCI) in July 2019 identified a critical need to collect, analyze, and share data to address the burden of cancer in children, adolescents and young adults. Currently, cancer registries in the United States hold structured information on every cancer case, including childhood cancers, within their respective catchment area. For childhood cancer patients and survivors, issues of late effects, recurrence, subsequent primary cancers, and follow-up are critically important to consider while addressing common instances of survivors moving to different states as these survivors mature and become adults. Using the data from registries as a base, an infrastructure that brings together key information on every childhood cancer patients and survivors.

The National Childhood Cancer Registry (NCCR) is envisioned as a connected data infrastructure to enable sharing of childhood cancer data from multiple and heterogeneous data sources. Incorporating available data on genomic and tumor characterization, residential history, social determinants of health and measures of financial toxicity, longitudinal treatments including oral agents, and longitudinal outcomes data including recurrence and subsequent cancers can enhance the core infrastructure of registry data on pediatric patients. Because the basis for the NCCR is existing central cancer registries, personally identifiable information (PII) is reportable to the central registry to permit longitudinal linkage and reporting to central registries is HIPAA exempt. The NCCR will 1) support relevant research on childhood cancers; 2) provide a potential sampling frame for additional research; and 3) provide a population level set of data on all childhood cancer patients, including patients who do not participate in clinical trials.

# **Purpose and Goals**

The National Cancer Institute (NCI), Division of Cancer Control and Population Sciences (DCCPS), announces the opportunity for supplemental funding for NCI-designated cancer centers to participate in the development of an infrastructure of combined data to establish a National Childhood Cancer Registry (NCCR). Supplemental funding will enable the cancer centers to aggregate, integrate, and submit their existing data beyond traditional cancer abstracts on childhood cancer patients under 19 years of age receiving care at the cancer center to the NCCR in order to expand that infrastructure and ultimately support research on childhood cancer. It will also facilitate the development of an ongoing submission process to the NCCR database for the continued submission of data on pediatric cancer patients.

The main goals of the one-year supplement are to 1) identify extensive detailed treatment and clinical data on pediatric patients not currently being reported to cancer registries, 2) complete an assessment of the quality of the data, and 3) to develop a data packaging and transfer mechanism to report the data to the NCCR. The expectation is to develop an ongoing data linkage with the NCCR that will supplement the data already being reported to the cancer registries.

Once the NCCR is established, we anticipate collaborations between cancer centers, local area providers, public health practitioners, and other public health professionals to utilize the centralized infrastructure to address questions related to childhood cancer patients with special attention to long term outcomes including recurrence and second primary cancers, detailed treatment information, and further characterization of the cancers.

# **Eligibility and Budget**

- This opportunity is open to all P30 Cancer Center Support Grants.
- Only one supplement request per center will be considered.
- Supplement requests may not exceed \$300,000 total costs, and the project period is for one year.
- Cancer centers whose P30 Cancer Center Support Grant will be in an extension at the time the award is made in FY20 are not eligible for this supplement.
- It is anticipated that awards for this supplement opportunity will be made in September 2020.

# **Application Submission Format**

Applications should be submitted as a signed, scanned PDF to Clara Lam (<u>clara.lam@nih.gov</u>) and Stacey Vandor (<u>stacey.vandor@nih.gov</u>) no later than COB May 4, 2020.

Email confirmation of application receipt from Stacey Vandor must be obtained to be officially considered and evaluated.

Requests must include the following:

- The Standard PHS 398 Face Page
- A detailed Budget and Budget Justification
- NIH Biographical Sketches for new key personnel proposed in the supplement
- Summary of the Project, not to exceed 5 pages (references are excluded from the 5-page limit; no appendices, please)

- Provide a detailed list and format of data items (including common data elements), data categories, and any other relevant information and documentation that are currently being collected by the cancer center. Examples of key data types would include but are not limited to: genomic and germline test results, detailed treatment information, participation in clinical trials, measures of social determinants of health related to the patient and family, longitudinal treatment including oral agents, longitudinal outcomes data including recurrence and subsequent cancers, other relevant patient information.
- Provide a background statement that explains how these existing data would provide important supplemental information to traditional cancer registry abstracts that will serve as the basis for the NCCR.
- Provide a work plan to complete data packaging and transfer from the cancer center to the NCCR database within the year of the supplement.
- Outline a work plan that provides a timeline for development of a process that would support submission of the data to the NCCR on an ongoing basis (e.g., staff involved, IT integration). It should include milestones (e.g., data completion assessment, data quality review, data packaging for transfer, data transfer completion) for tracking the progress of the work in the one year of the supplement.
- Include agreement to attend two in-person meetings during the supplement period to establish and participate in working groups to address standardization of common data elements, data

harmonization, specific research and clinical questions that can be addressed by the NCCR, and other relevant topics.

• Describe the qualifications of the individual(s) who will conduct the work. Briefly elaborate on each person's CV in the narrative response.

## **NCI Evaluation of Supplement Requests**

Administrative supplements do not receive peer review. Instead, NCI staff with expertise in cancer prevention and control will evaluate supplement requests to determine overall merit. Proposals will be reviewed for quality and for responsiveness to application criteria outlined in the requirements for the five-page summary described above.

#### **Reporting Requirements**

As part of the progress report for the parent cancer center grant, information must be included on what has been accomplished via the administrative supplement (program details such as workflow incorporation, sustainability actions, progress on timeline tasks, and other noted measures). Project leaders will participate in calls and meetings where they will be expected to present their progress and findings to NCI, other supplement awardees, and representatives from other NCI-Designated Cancer Centers. Award recipients are expected to provide data to NCI evaluators when requested.

#### **Pre-Submission Informational Webinar:**

An informational webinar will be held as noted below:

Time: Wednesday, March 18, 2020, 12:00 PM Eastern Time (US and Canada)

The registration link is as follows:

https://cbiit.webex.com/cbiit/onstage/g.php?MTID=efd5d082d707e740d9e21c3b1a67209c1

Dial-in information:

Call-in toll number (US/Canada)

1-650-479-3207

Meeting Number/Access Code: 739 299 805

Event password: J2d5pEBZw\$6

#### Questions

For technical inquires (including eligibility), please contact your cancer center support grant administrator or your NCI program director. For inquiries about the scientific objectives and goals, please contact Clara Lam (clara.lam@nih.gov).

# Administrative Supplements for the NCI P30 Cancer Center Support Grants to support community outreach and engagement (COE) activities across the translational research continuum

## Background

Community outreach and engagement (COE) has been a fundamental activity of National Cancer Institute (NCI)-designated Cancer Centers since the initiation of the Cancer Centers program in 1971. Historically, COE has been commonly considered an extension of Centers' Population Science/Cancer Prevention and Control Research Programs. However, since the 2016 and 2019 reissuances of the P30 Cancer Centers Support Grant (CCSG) guidelines, COE is expected to now span all aspects of Centers' programs, including basic, clinical, translational, and population research. Cancer Centers – working with community stakeholders – should identify community needs, communicate those needs across the Center's leadership and research programs (i.e., "in-reach"), and catalyze activities of special relevance to the Cancer Center's self-defined geographic catchment area population. Cancer Centers are encouraged to generate examples of research projects where outreach to and engagement of communities informed and resulted in high-impact science. In addition, Centers are expected to work with communities to disseminate and implement evidence-based interventions (EBIs) and guidelines, public education, and public health policy recommendations. This bidirectional relationship between communities and Cancer Centers promotes an understanding of cancer that is more holistic (bench-tobedside-to-community), transdisciplinary, encompassing of different views and experiences, culturally sensitive, and reflective of mutual goals.

### **Purpose and Goals**

Cancer Center COE activities have made meaningful contributions to participant recruitment into therapeutic and behavioral intervention studies. However, there has been less focus on COE contributions to either basic science or translating EBIs into community practice. The National Cancer Institute (NCI), Division of Cancer Control and Population Sciences (DCCPS), announces the opportunity for supplemental funding for NCI-designated cancer centers to build capacity for COE activities that address two distinct areas of the translational research continuum: basic science and public/community health.

Supplement proposals must focus on one of the following areas.

- 1) COE activities are well aligned with Population Science/Cancer Prevention and Control Research Programs given the shared emphasis on implementation science, public health research and practice, health communication, health policy, community-based participatory research, and cancer disparities, among other priorities. However, integrating COE into other Center Research Programs may be more challenging due to: basic science investigators' limited knowledge of COE principles and methods; the time, dedication, and relationship building that COE requires; differences in research targets and outcomes (e.g., genes vs. cells vs. communities); communities' limited understanding of basic research; and inaccurate perceptions that COE is not relevant to basic biomedical sciences and vice versa. This option is designed to help bridge the divide and increase NCI-designated Cancer Centers' transdisciplinary capacity for engaging in bidirectional linkages between COE-related activities, community stakeholders, and basic research programs and investigators. Centers who choose this option must develop, pilot, and evaluate a 1-year capacity building project that either serves to initiate a new collaboration between COE, community partners, and one of the Center's basic research programs or enhance an existing collaboration.
- 2) Cancer Centers have a history of generating EBIs through efficacy and effectiveness research, particularly through their Population Science/Cancer Prevention and Control Research Programs. Subsequently, through COE activities, Centers now have an enhanced opportunity to translate that research into practice with an implementation science lens. The purpose of this option is to understand how COE programs at NCI Cancer Centers work with community partners to identify, adapt, and implement existing EBIs to meet the needs of the communities that they serve. EBIs could be identified from interventions developed at the Cancer Center or from existing repositories.

For example, EBIs can be found on NCI's Research-tested Intervention Programs (RTIPS) website (<u>https://rtips.cancer.gov/rtips/index.do</u>), which is designed to provide cancer control researchers and practitioners with access to EBIs that have outcomes published in peer-reviewed journals and tangible products that can be implemented in practice. Similarly, The Community Guide (<u>https://www.thecommunityguide.org/</u>) uses a science-based approach to determine whether an intervention approach works and is cost-effective. Although these EBI repositories are available for widespread use, it is unclear how many EBIs are put into practice by Cancer Center COE programs (either alone, or more commonly, in partnership with other organizations), and if they are, how they are adapted, implemented, and evaluated. Centers who choose this option must conduct a 1-year project that assesses how Cancer Centers identify, adapt, implement, and evaluate existing EBIs in collaboration with community stakeholders.

This supplement initiative is a part of a larger NCI research initiative to engage Cancer Centers and communities in collaborative, translational research focused on decreasing the cancer burden across the U.S., including among minority and underrepresented populations. It also supports the current P30 CCSG guidance wherein Cancer Centers are encouraged to describe knowledge, best practices, and tools developed by COE activities, and to share these with other NCI Cancer Centers. Centers will collaborate across the funded consortium of NCI Cancer Centers, sharing best practices for: training activities, data collection, evaluation metrics, partnership models, working with underserved populations, etc. The long-term goal of this administrative supplement opportunity is to build capacity for Cancer Centers' COE programs to adapt and implement evidence-based programs and successfully collaborate with Cancer Center investigators across research programs and in partnership with community members. The projects proposed will serve as a model or use-case for subsequent COE initiatives conducted within the Cancer Center as well as across the NCI Cancer Centers community.

# **Eligibility and Budget**

- This opportunity is open to currently funded clinical and comprehensive NCI-designated cancer centers.
- Only one supplement request per center will be considered.
- To be considered responsive for supplemental funding, centers must choose one of the two options described above and articulate a detailed project plan.
- Supplement requests may not exceed \$150,000 total costs, and the project period is for one year.
- Cancer centers whose P30 Cancer Center Support Grant will be in an extension at the time the award is made in FY20 are not eligible for this supplement.
- It is anticipated that awards for this supplement opportunity will be made in September 2020.

# **Application Submission Format**

Applications should be submitted as a signed, scanned PDF to Robin Vanderpool (robin.vanderpool@nih.gov) and Stacey Vandor (<u>stacey.vandor@nih.gov</u>) no later than COB May 4, 2020.

Email confirmation of application receipt from Stacey Vandor must be obtained to be officially considered and evaluated.

Requests must include the following:

- The Standard PHS 398 Face Page
- A detailed budget and budget justification
- NIH Biographical Sketches for new key personnel proposed in the supplement
- Summary of the Project, not to exceed 5 pages (references are excluded from the 5-page limit; no appendices, please)

- Provide a brief description of the Cancer Center's catchment area and how analysis of catchment area data informed the cancer research priorities being addressed by the project.
- Include a brief overview of the Center's COE infrastructure and the relevant basic science research program or the Population Science/Cancer Prevention Control Research Program.
- Provide a clear overview of the proposed project, articulating Option 1 or Option 2 as described above.
- Provide a description of the involved community stakeholder(s) and organization(s).
- Briefly explain the process to engage researchers and community stakeholders around a common understanding of the shared goals of the project, COE and scientific terminology and methodologies, how to translate research into practice, and/or one another's perspectives on the cancer research priorities to be addressed.
- Outline a work plan that provides a timeline and milestones for the proposed 1-year supplement activities.
- Provide a systematic evaluation of the proposed supplement activities.
- Briefly describe preliminary plans for continuing to grow and develop the proposed body of COE work beyond the supplement funding period.
- Describe the qualifications for the identified lead(s) of the supplement.
- Provide a budget that includes funds to support the travel of two project team members to attend the annual Cancer Center Community Impact Forum (CCCIF) meeting.

# **NCI Evaluation of Supplement Requests**

Administrative supplements do not receive peer review. Instead, NCI staff with expertise in cancer prevention and control will evaluate supplement requests to determine overall merit. Proposals will be reviewed for quality and for responsiveness to application criteria outlined in the requirements for the 5-page summary described above.

#### **Reporting Requirements**

As part of the progress report for the parent CCSG, information must be included on what has been accomplished via the administrative supplement (program details such as trainings; tactics implemented; sustainability actions; progress on timeline tasks; and results from evaluation measures on reach, uptake, and other noted measures) as well as progress on the Cancer Center's work and future development plans. Each Cancer Center that is awarded a supplement will be expected to provide a case study that will be shared among the Cancer Center community. NCI will provide a template that may be used for the case study. Project leaders (at least two from each cancer center) should plan to attend the annual CCCIF meeting, where they will be expected to present their findings to other awardees of these supplements.

#### **Pre-Submission Informational Webinar:**

An informational webinar will be held as noted below:

Time: Wednesday, March 18, 2020, 12:00 PM Eastern Time (US and Canada)

The registration link is as follows:

https://cbiit.webex.com/cbiit/onstage/g.php?MTID=efd5d082d707e740d9e21c3b1a67209c1

Dial-in information:

Call-in toll number (US/Canada)

1-650-479-3207

Meeting Number/Access Code: 739 299 805

Event password: J2d5pEBZw\$6

# Questions

For technical inquiries (including eligibility), please contact your CCSG administrator or your NCI program director. For inquiries about the scientific objectives and goals of this administrative supplement, please contact Robin Vanderpool (robin.vanderpool@nih.gov).

# Administrative Supplements for the NCI P30 Cancer Center Support Grants to address financial hardship during cancer treatment

## Background

Cancer-related financial hardship, including financial toxicity due to drug costs and the other direct and indirect costs of cancer treatment, is an increasingly common experience for patients and their caregivers. Patients are responsible for an ever-growing share of the cost of their cancer care, paying more for medical appointments, imaging, tests, and procedures. Additionally, the high cost of breakthrough therapies is frequently more expensive than most patients can afford without substantial detriment to their financial well-being. Financial hardship is associated with delaying the start of recommended treatments as well as treatment non-adherence. As the costs of cancer care accumulate, patients are forced to make difficult trade-offs, including delaying or forgoing recommended care due to budget constraints. Further, financial hardship is a major source of stress, leading to poor patient outcomes and diminished quality of life. The impact of financial hardship is cumulative and long-lasting, with consequences extending well beyond the period of active treatment. The patients at greatest risk for financial hardship are often vulnerable sub-groups who already face obstacles to high quality care.

The causes of cancer-related financial hardship are multifaceted, stemming from high out-of-pocket costs, inadequate insurance coverage, missed days from work or job loss, and other related challenges. Thus, a program of services is needed to address this complex problem. A 2019 survey sponsored by the National Cancer Institute (NCI) Division of Cancer Control and Population Sciences (DCCPS) suggested that most NCI-designated Cancer Centers offer a range of financial navigation services including help applying to pharmaceutic company-sponsored patient assistance programs, financial assistance to manage non-medical costs, help applying for health insurance coverage and help understanding medical bills. However, 40% of Centers reported a lack of staff awareness about available financial navigation services and 46% reported that the pathways or workflows to connect cancer patients with existing financial services were unclear. Additionally, over 50% of Centers reported that patients were reluctant to ask for financial help when they needed it and 37% of Centers could not estimate the percentage of their patients who experience cancer-related financial hardship. Collectively, these findings suggest a need to both enhance the systematic identification of patients experiencing financial hardship and improve the coordination and delivery of financial navigation services. This supplement initiative will help Cancer Centers to develop or expand their capacity and infrastructure to deliver financial navigation services and to collect the preliminary data necessary to more broadly implement and evaluate financial navigation programs.

# Definitions:

<u>Financial hardship</u> is an umbrella construct, encompassing (1) *material conditions* caused by high out-of-pocket costs, missed work, reduced income, and medical debt and bankruptcy; (2) the *psychological response* or worry resulting from paying medical bills or concerns about lost wages; and (3) *coping behaviors* to manage out-of-pocket medical expenditures, such as skipping medication or delaying or forgoing recommended care to save money.

<u>Financial navigation</u> refers to processes by which patients and their families are aided in affording care after a cancer diagnosis to avoid adverse financial consequences and hardship associated with cancer treatment, including education about and assistance with accessing appropriate financial programs and services.

<u>Medical care costs</u> include out-of-pocket costs for drugs, procedures, therapies, healthcare visits and hospital stays; expenses incurred as a direct result of pursuing cancer treatment (e.g., transportation to and from the hospital, family care, caregiving, special clothing, wigs, and medical supplies); and lost wages due to missed work or job loss.

#### **Purpose and Goals**

The National Cancer Institute (NCI), Division of Cancer Control and Population Sciences (DCCPS), announces the opportunity for supplemental funding for NCI-designated cancer centers to develop or expand their capacity and necessary infrastructure to deliver evidence-based financial navigation services. It is expected that this work will inform the development and expansion of research to inform the financial navigation program within the Cancer Center to decrease cancer-related financial hardship among patients and their families.

The short-term goal of these supplements is to provide resources to support the time and effort of teams at NCI-designated Cancer Centers to develop or expand their capacity to proactively identify patients who are at risk for, concerned about, or actively experiencing financial hardship because of the cost of their medical care and to provide appropriate financial navigation services throughout the cancer care continuum. Proactive screening can be conducted in the context of distress screening or other assessment or through the development and implementation of a new screening tool. Screening results should be used to identify patients in need and inform the delivery of appropriate services. Projects funded under this initiative may be conducted in a single clinic or among patients with a particular cancer or receiving a particular treatment. Projects may also focus on screening during a particular time point during treatment planning or care delivery.

NCI will consider requests for supplements for the following types of activities:

- Analyses of local data focusing on identifying opportunities to improve financial navigation interventions.
- Implementation of evidence-based tools and approaches that could be used to identify patients at risk for, concerned about, or experiencing financial hardship.
- Orienting medical or non-medical personnel to the scope of available services available within the Cancer Center to address aspects of financial hardship, and how to access those services.
- Evaluating the reach of financial hardship screening and the impact on patient and care delivery outcomes.
- Analyzing existing staffing models, clinic processes, infrastructure, and patient needs to identify strategies to improve and document the delivery of financial navigation services.
- Developing and pilot testing new pathways/workflows to connect patients with financial navigation, social work and other assistance within the Cancer Center.
- Developing standards for documenting screening results in the EHR to facilitate research and practice improvement.
- Building capacity within Cancer Center IT systems to track patients' financial hardship over time, referrals for and utilization of financial navigation services, and patient outcomes.

The long-term goal is to build or expand the infrastructure needed to sustain a financial navigation program beyond the length of the supplement. It is expected that Cancer Centers will build upon their supplement project, gather preliminary evidence, and apply for future funding to support research to inform the expansion or scale-up of proactive screening for financial hardship and service delivery as well as test new models of financial navigation and counseling and evaluate patient outcomes.

# **Eligibility and Budget**

- This opportunity is open to all clinical and comprehensive P30 Cancer Center Support Grants.
- Only one supplement request per center will be considered.
- Supplement requests may not exceed \$150,000 total costs, and the project period is for one year.
- Cancer centers whose P30 Cancer Center Support Grant will be in extension at the time the award is made in FY20 are not eligible for this supplement.
- It is anticipated that awards for this supplement opportunity will be made in September 2020.

#### **Application Submission Format**

Applications should be submitted as a signed, scanned PDF to Janet de Moor (janet.demoor@nih.gov) and Stacey Vandor (<u>stacey.vandor@nih.gov</u>) no later than COB May 4, 2020.

Email confirmation of application receipt from Stacey Vandor must be obtained to be officially considered and evaluated.

Requests must include the following:

- The Standard PHS 398 Face Page
- A detailed budget and budget justification
- NIH biographical sketches for key personnel proposed in the supplement
- Summary of the project (not to exceed 5 pages) (references are excluded from the 5-page limit; no appendices, please)

The 5-page summary must:

- Describe how the proposed project will leverage existing services or resources offered in the Cancer Center to address financial hardship and the staff involved in delivering those services.
- Provide a rationale for the clinic or patient population in which the work will be conducted.
- Describe the process that the project team will use to develop or expand and implement financial hardship screening and delivery of financial navigation services. This should include:
  - how the project will address potential patient, provider, and clinic barriers to proactive screening and subsequent service delivery;
  - the types of services that may be offered, tested, expanded, or adapted;
  - how the activities within the proposed project will inform the organization's ability to fit services into existing provider and/or administrative workflows; and
  - how staff will engage patients, at what points during treatment and survivorship care; and how and by whom follow-up will be conducted and monitored.
- Outline a work plan that provides a timeline for development and implementation of the project (such as staff involved, staff training and hiring plans, IT integration). It should include milestones for tracking the progress of the work in the one year of the supplement.
- Provide an evaluation plan for the project including primary and secondary outcomes at the patient, provider, and system level.
- Describe plans to collect preliminary data for future research proposals or pilot projects to improve the delivery financial navigation services.
- Describe of the qualifications for the identified lead(s) of the program.
- Include funding to attend an in-person grantee meeting to discuss lessons learned from the project.

# **NCI Evaluation of Supplement Requests**

Administrative supplements do not receive peer review. Instead, NCI staff with expertise in cancer prevention and control will evaluate supplement requests to determine overall merit. Proposals will be reviewed for quality and for responsiveness to application criteria outlined in the requirements for the five-page summary described above.

# **Reporting Requirements**

As part of the progress report for the parent Cancer Center grant, information must be included on what has been accomplished through the administrative supplement (e.g., program details such as conceptual framework; approaches developed and implemented; workflow incorporation; progress on timeline tasks; and results from the evaluation of screening and service delivery outcomes), as well as progress on the Cancer Center's work.

# Pre-Submission Informational Webinar:

An informational webinar will be held as noted below:

Time: Wednesday, March 18, 2020, 12:00 PM Eastern Time (US and Canada)

The registration link is as follows: <u>https://cbiit.webex.com/cbiit/onstage/g.php?MTID=efd5d082d707e740d9e21c3b1a67209c1</u>

Dial-in information:

Call-in toll number (US/Canada)

1-650-479-3207

Meeting Number/Access Code: 739 299 805

Event password: J2d5pEBZw\$6

#### Questions

For technical inquiries (including eligibility), please contact your cancer center grant administrator or your NCI program director. For inquiries about the scientific objectives and goals, please contact Janet de Moor (janet.demoor@nih.gov).

# Administrative Supplements for the NCI P30 Cancer Center Support Grants to investigate vaccine hesitancy related to uptake of the HPV vaccine in regions with low adolescent HPV vaccination rates

## Background

In January 2019, the World Health Organization (WHO) released a list of ten global health threats that included vaccine hesitancy, placing it on the same threat level as climate change (WHO/Rada Akbar. *Ten Threats to Global Health in 2019.* <u>www.who.int/emergencies/ten-threats-to-global-health-in-2019</u>).</u> WHO described vaccine hesitancy as "the reluctance or refusal to vaccinate despite the availability of vaccines and threatens to reverse progress made in tackling vaccine-preventable diseases."

HPV vaccine uptake rates in the US continue to be well below established goals – 2018 data from the NIS Teen survey show just over 50% of adolescents ages 13-17 were fully vaccinated against HPV in 2018. (https://www.cdc.gov/mmwr/volumes/68/wr/mm6833a2.htm?s\_cid=mm6833a2\_w). The Centers for Disease Control and Prevention (CDC) estimates that increasing HPV vaccination rates from current levels to 80 percent would prevent an additional 53,000 future cervical cancer cases in the United States among girls who are currently 12 years old or younger over the course of their lives. Thousands of cases of other HPV-associated cancers in the U.S. would also likely be prevented within the same timeframe.

In 2016, the Vice President's Cancer Moonshot was established with a goal of achieving "a decade's worth of progress in preventing, diagnosing, and treating cancer in five years, ultimately striving to end cancer as we know it." The <u>Cancer Moonshot Blue Ribbon Panel Report</u> highlights increasing HPV vaccination as an area in which the effectiveness for cancer prevention is well known, but where implementation is unacceptably low. Advances in implementation would prevent additional cancer cases and unnecessary deaths. Implementation research is needed to accelerate the development and testing of effective strategies to achieve wider adoption and sustainability of evidence-based approaches, especially among populations that suffer a disproportionate burden of HPV-related cancers.

Prior cancer center supplements on HPV vaccine have focused on missed clinical opportunities and the quality of the provider recommendation for the vaccine. Although those factors continue to be important, the most recent CDC reports on HPV vaccination rates stressed that "... even when a provider recommendation was given, only 75% accepted the vaccine, suggesting that there are other reasons adolescents are not being vaccinated. Equipping providers with the tools they need to give strong recommendations that emphasize the importance of HPV vaccination in preventing cancer and effectively address parental concerns is a priority, especially in states where provider recommendations were less commonly reported.

In 2018, nationwide, the number of 13- to 17-year-old boys and girls getting the human papillomavirus (HPV) vaccine remained steady with previous years' assessments, per data from CDC's 2018 National Immunization Survey-Teen (NIS-Teen) (MMWR, August 23, 2019). However, there was significant variation across the country with some states – or cities – achieving much larger increases in HPV vaccine coverage and others falling further behind.

This variation suggests that local barriers to vaccine uptake need to be better understood. These could include, for example, community attitudes in opposition to vaccination generally or the HPV vaccine specifically; the effects of local opinion leaders; diffusion of vaccine-related misinformation on social media; in addition to long-standing access and healthcare delivery-based barriers. Similarly, local facilitators such as active vaccine champions, parent groups, and well-coordinated efforts within or across state or local health departments may already be present to support vaccine promotion efforts. To address vaccine hesitancy and its effects on vaccine uptake at the community level, local-level investigation is needed to characterize local vaccine hesitancy and other barriers, as well as facilitators, and existing vaccine promotion efforts.

### **Purpose and Goals**

The National Cancer Institute (NCI), Division of Cancer Control and Population Sciences (DCCPS), announces the opportunity for supplemental funding for NCI-designated cancer centers to investigate vaccine hesitancy. The purpose is to characterize and understand the influence of vaccine hesitancy on HPV vaccine uptake in regions of the US where adolescent uptake is low. The goals for this one-year supplement are to understand characteristics of vaccine-hesitant communities within the cancer center catchment area, to identify promising and innovative approaches to reducing hesitancy and other barriers to HPV vaccination, and to gather pilot data to support future interventions towards reducing vaccine hesitancy and increasing HPV vaccination. Preference will be given to centers that identify, within the cancer center catchment area, a region or population with low uptake, as documented by local surveillance or results from the <u>2018 NIS-Teen</u>. These supplements are part of a larger effort that NCI and CDC's Division of Cancer Prevention and Control are undertaking, which is a more systematic effort to bring together NCI cancer centers, CDC programs, and state/local health departments and their immunization programs.

# **Eligibility and Budget**

- This opportunity is open to all clinical and comprehensive P30 Cancer Center Support Grants located in or demonstrating the ability to work in regions with low HPV vaccine uptake, including those that have received a previous supplement for HPV Vaccine Uptake.
- Only one supplement request per center will be considered.
- Supplement requests may not exceed \$200,000 total costs, and the project period is for one year.
- Costs must be primarily associated with data collection activities (include minimal investigator time and no conference travel)
- Travel costs will only be covered if directly associated with data collection.
- Cancer centers whose P30 Cancer Center Support Grant will be in extension at the time the award is made in FY20 are not eligible for this supplement.
- It is anticipated that awards for this supplement opportunity will be made in September 2020.

# **Application Submission Format**

Applications should be submitted as a signed, scanned PDF to Cynthia Vinson (<u>cvinson@mail.nih.gov</u>) and Stacey Vandor (<u>stacey.vandor@nih.gov</u>) no later than COB May 4, 2020.

Email confirmation of application receipt from Stacey Vandor must be obtained to be officially considered and evaluated.

Requests must include the following:

- The Standard PHS 398 Face Page
- A detailed budget and budget justification
- NIH biographical sketches for key personnel proposed in the supplement
- Summary of the project (not to exceed 5 pages) (references are excluded from the 5-page limit; no appendices, please)

- Provide a statement of need that defines a region or population within the cancer center catchment area with documented low adolescent HPV vaccine uptake.
- Document ability and expertise to work in that region or population, e.g., ease of access, familiarity with local data, as well as political, social, and other contextual characteristics.
- Describe the processes that will be used for identifying HPV vaccine-hesitant populations, characterizing local factors that influence the hesitancy, and identifying innovative intervention approaches.
- Describe processes that will be used to identify innovative interventions, in the identified HPV vaccine-hesitant population, including variables that can be measured at different levels, for

example: parents, providers, clinic staff, community members, local social media, local mass media, and other sources of influence on vaccine hesitancy.

- Describe pilot data that will be collected to support future interventions.
- Describe the qualifications of the individual(s) who will conduct the work. Briefly elaborate on each person's CV in the narrative response.

#### **NCI Evaluation of Supplement Requests**

Administrative supplements do not receive peer review. Instead, NCI staff with expertise in cancer prevention and control will evaluate supplement requests to determine overall merit. Proposals will be reviewed for quality and for responsiveness to application criteria outlined in the requirements for the five-page summary described above.

### **Reporting Requirements**

As part of the progress report for the parent cancer center grant, include information on what has been accomplished via the administrative supplement, including populations identified as vaccine hesitant and the influences on that hesitancy; interventions identified for testing in order to decrease hesitancy and increase HPV vaccine uptake among those populations; and any pilot data collected (e.g., evidence of feasibility and acceptability); as well as the cancer center's plans to move forward on HPV vaccination hesitancy issues and the platform it will use to further progress around HPV vaccination. Award recipients are expected to provide data to NCI evaluators when requested.

#### **Pre-Submission Informational Webinar:**

An informational webinar will be held as noted below:

Time: Wednesday, March 18, 2020, 12:00 PM Eastern Time (US and Canada)

The registration link is as follows:

https://cbiit.webex.com/cbiit/onstage/g.php?MTID=efd5d082d707e740d9e21c3b1a67209c1

Dial-in information:

Call-in toll number (US/Canada)

1-650-479-3207

Meeting Number/Access Code: 739 299 805

Event password: J2d5pEBZw\$6

#### Questions

For technical inquiries (including eligibility), please contact your cancer center grant administrator or your NCI program director. For inquiries about the scientific objectives and goals, please contact Sarah Kobrin (kobrins@mail.nih.gov).