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. 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. 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. 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. 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; CDC's Behavioral Risk Factor Surveillance System 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

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

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 (ellisong@mail.nih.gov) and Stacey Vandor (stacey.vandor@nih.gov) 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:
- 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:
  - 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).