# Key Details and Frequently Asked Questions for RFA-CA-22-052

| Key Details: RFA-CA-22-052 Cannabis and Cannabinoid Use in Adult Cancer Patients During Treatment: Assessing Benefits and Harms (U01 Clinical Trial Not Allowed) | |
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| **Mechanism** | U01 |
| **Leadership** | Single or Multiple PI |
| **Clinical Trial Requirement** | Not Allowed |
| **Aims** | This Funding Opportunity Announcement (FOA) requests applications to support observational research studies to assess the benefits and harms of cannabis and cannabinoid use among cancer patients in active treatment. This FOA supports well-designed prospective cohort studies of patients with solid or hematologic tumors, currently receiving treatment, comparing those using with those not using cannabis or cannabinoids. |
| **Populations** | Research must focus on cancer patients in active treatment comparing those who use cannabis/cannabinoids to those not using cannabis and/or cannabinoids. |
| **Study Requirements** | To be responsive to this FOA, proposed projects must include:<br>• Scientific justification of the research gaps to be addressed related to understanding the benefits and harms of cannabis and cannabinoid use among cancer patients in active treatment.<br>• Prospective cohort study design of cancer patients in active treatment comparing those who use cannabis/cannabinoids to those not using cannabis and/or cannabinoids. Cancer patients undergoing active treatment (surgery and/or radiation and/or other systemic therapy). Follow-up of cancer patients may continue beyond the active treatment period.<br>• Justification of the study population and sample size given the proposed science. If the participants are outside the US, justification needs to address relevance to the US population.<br>• Detailed information on the types and patterns of cannabis and cannabinoid uses among cancer patients, purpose of use, and associated outcome measures. This information should include the types and source of products used, the mode of administration as well as the frequency and dose, and to the extent possible, what active ingredients are included (e.g., THC to CBD, ratios between the two compounds). The collection of this information should be as detailed as possible and may include patient-report of cannabis and cannabinoid use, specific products used, and products sources (medical dispensaries and other sources).<br>• Detailed information on patient demographics, social determinants of health, clinical and disease characteristics, co-morbidities, and inpatient and outpatient cancer treatments and oral therapies should be obtained from medical (e.g., electronic health records and/or other |

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| | medical records), and/or pharmacy records. Additional information can be obtained from patient reports.<br>• Patients' use of medications and other complementary and alternative medicines used to manage symptoms should be obtained.<br>• Validated patient symptom surveys that measure the presence and severity of symptoms over time should be used. High-quality data should be collected using validated methods and instruments and evidence-based approaches (e.g., abstraction of detailed treatment data, NIH Common Data Elements, Patient-Reported Outcomes Measurement Information System [PROMIS]).<br>• Data collected from routine clinical monitoring (e.g., kidney and liver function, blood cell count).<br>• Measurement of cannabis use disorder through surveys or other techniques.<br>• Willingness to collaborate on collecting a core set of questions related to cannabis and cannabinoid use and other survey measures (e.g., health outcomes, patient-reported outcomes) in cancer patients in active treatment.<br>• If biospecimen assays are proposed, evidence of reproducibility and validity must be included in the grant application.<br>• Detailed data/resource sharing plans that are consistent with NIH policy and follow Findable, Accessible, Interoperable, Reusable (FAIR) principles (see https://www.go-fair.org/fair-principles/) for Resource Sharing Plans as provided in SF424 Application Guide. The data sharing plan must describe the management and decision-making process that promotes rapid data sharing with the broad research community, the timeline for sharing, the repository where the data will be located, process for accessing data, and any limitations. The plan should also include steps for creating standard operating procedures, accessibility requirements, and review process for granting access to the research community and dissemination of that information. The data sharing plan will become a term and condition of award. Applicants are required to provide broad access to the data through controlled-access data repositories. Applicants are encouraged to consider NIH data repositories for sharing data with external investigators. Informed consent must include permission to share de-identified data with the broad research community and deposit to a controlled-access repository. If non-NIH repositories need to be selected, these must be publicly accessible or controlled access.<br>(See www.nlm.nih.gov/NIHbmic/nih_data_sharing_repositories.html for a full listing of NIH repositories). |
| **Budget Considerations** | Application budgets are limited to $500,000 direct costs per year. |
| **Scientific Contacts** | Dr. Kelly Filipski (Kelly.Filipski@nih.gov) |

*Application FAQs*

**Is a letter of intent required and by what deadline? What should be included?**

Yes. A letter of intent (LOI) is strongly encouraged. LOIs assist NCI in preparing and planning for review. With this information, NCI can assess workload (e.g. how many applications will be reviewed) and allow us to begin identifying expert reviewers without conflicts of interest. Letters of intent are due on January 18, 2023.

Letters of intent should include the following:

- Descriptive title of proposed activity
- Specific Aims for the proposed project
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)

Names of other key personnel

- Participating institution(s)
- Number and title of this funding opportunity

The LOI should be sent by email, with the subject "Letters of Intent for RFA-CA-22-052 and RFA-CA-22-053" to Kelly.Filipski@nih.gov

**Are applications with a clinical trial design permitted to apply?**

No, clinical trials are not allowed for these Requests For Applications (RFAs).

**Will there be additional rounds of funding?**

No, at the current time, we only have approval and funding for one round.

**Are foreign institutions allowed to apply? What about foreign partners and/or subcontracts?**

Foreign institutions, partners and subcontracts are eligible to apply for grants under RFA-CA-22-052. However, foreign institutions, partners and subcontracts are not eligible to apply for the coordinating center (RFA-CA-22-053).

**How will Early-Stage Investigator (ESI) status be incorporated into the review process and funding decision, if at all?**

ESI-submitted applications will not be reviewed separately from the established investigator applications in the Special Emphasis Panel. We will consider early-stage investigator status as a factor in our funding decisions.

**Can you say more about what should be included in the data sharing plan?**

All applications, regardless of the amount of direct costs requested for any one year, should include a Data Sharing Plan that is compliant with the current NIH Data Management and Sharing Policy and, if applicable, the Genomic Data Sharing Policy. Please see the NIH Scientific Data Sharing webpage for additional information. Please note that there is a new NIH Data Management and Sharing Policy for applications submitted on or after January 25, 2023.

**How many submission dates are there?**

There is only one submission date – February 17, 2023. Please see the RFA announcements in the NIH Guide for more information (RFA-CA-22-052, RFA-CA-22-053).

**Are resubmissions allowed?**

Applications that are submitted but not funded for the submission due date (February 17, 2023) are encouraged to resubmit their applications as new applications to other FOAs (e.g., NIH Parent R01 FOA, PA-20-185, PA-20-183).

**Will the grants be reviewed in a special study section?**

Yes, the RFA applications will be reviewed in a special study section for those applications submitted to this FOA.

**How will funding decisions be made?**

After the peer review, Program will propose a funding plan based on scientific and technical merit of the proposed project and the relevance of the project to program priorities. The funding plan will then be reviewed by NCI senior leaders and the National Cancer Advisory Board.

**What is the payline for this RFA?**

RFAs do not have established paylines. After the peer review, Program will propose a funding plan based on scientific and technical merit of the proposed project and the relevance of the project to program priorities. The funding plan will then be reviewed by NCI senior leaders and the National Cancer Advisory Board.

**Can the same research team submit proposals to both the U24 and U01 RFAs?**

Yes, the same team can submit proposals to both RFAs, though NCI would only fund either the U01 or U24.

**Should the U01 applications utilize the multiple principal investigator mechanism?**

The study team needs to be representative of the proposed science and have the expertise to support study implementation and analysis. The investigators' biosketches need to effectively communicate their individual expertise to the per review. Teams utilizing the multiple PI mechanism need to include a MPI leadership plan in the application.

***Research Scope FAQs***

**What do you mean by "active treatment"?**

Cancer patients enrolled during active treatment include those undergoing surgery and/or radiation and/or other systemic therapy, including those with recurrent/metastatic disease. Follow-up of cancer patients may continue beyond the active treatment period.

**How detailed should be the collection of cannabis/cannabinoids use?**

This information should be as detailed as possible and include the types and source of products used, the mode of administration as well as the frequency and dose, and to the extent possible, what active ingredients are included (e.g., THC to CBD, ratios between the two compounds)

Collection may include patient-report of cannabis and cannabinoid use, specific products used, and products sources (medical dispensaries and other sources).

Biological specimen analysis for THC and/or CBD levels are also permitted, but investigators will need to address the issues of current lack of measurement standards, legality status and confidentiality, and challenges with timing of specimen collection and cannabis and cannabinoids.

**How detailed should be the collection of information on clinical and disease characteristics, co-morbidities, and inpatient and outpatient cancer treatments and oral therapies?**

This information should be as detailed as possible and should be obtained from medical (e.g., electronic health records and/or other medical records), and/or pharmacy records. Additional information can be obtained from patient reports.

**Is there a specific cancer type(s) or stage of cancer that are of higher priority?**

There is no specific cancer type, cancer types or stages that are of higher priority than others. However, the applicant must justify the inclusion of the specific population or populations under study. Patient populations undergoing systemic chemotherapy and / or immunotherapy are strongly encouraged.

**Are studies utilizing pediatric or childhood cancer populations appropriate for this RFA?**

Applications focusing on pediatric or childhood cancer populations are not responsive to this RFA. This RFA is focused on adult cancer patient populations defined as 18 years and older.

**How much preliminary data is needed for this RFA?**

The U01 mechanism is meant for well-developed projects supported by preliminary data. Reviewers will evaluate the application for scientific merit, which includes an assessment of the rigor of the prior research that serves as the scientific premise for the proposed project. Preliminary data should be sufficient to support gaps in the premise of the proposed project and/or demonstrate that your proposed research is promising and that your ability to carry it out is credible (e.g., demonstrating a proof of concept or expertise for a technique).

**Can NCI Community Oncology Research Program (NCORP) be used for patient recruitment?**

Please contact Dr. Kelly Filipski at Kelly.Filipski@nih.gov to set up a meeting with the NCORP program officers to discuss the feasibility of this approach.

**I have specific questions about my project. What should I do?**

Please email Dr. Kelly Filipski at Kelly.Filipski@nih.gov to discuss project specific questions and include an abstract/specific aims.