

Cancer Care Network / NCORP

A member of the NCI Community Oncology Research Program

The COSMIC-ReLeaf™ Study¹ wants to know how patients using cannabis manage their cancer-related symptoms.

You may be eligible to join the study if you meet the following eligibility criteria:

- Patients must be 18 years of age or older and able to give verbal informed consent to participate.
- Patients must be able to speak, read and understand English.
- Patients must report use of cannabis at time of study participation.
- Patients must have access to internet and ability to download Releaf™ App (MoreBetter, Ltd.) to a smartphone or tablet and must use Releaf™ App (MoreBetter, Ltd.) for cannabis journaling.
- Patients must be able to send and receive text messages, and be able to interact with web-pages on smartphone or tablet.
- There are 2 scenarios that patients are eligible for participation, and are listed below:
 1. Patients must have a cancer diagnosis for which they are receiving active therapy defined as follows:
 - Surgery – must be within a 30-day pre- and/or post-operative (peri-operative) window if single modality of care.
 - Radiation – must be within a 30-day pre- (simulation planning phase) and/or post-radiation window if single modality of care.
 - Any anticancer systemic therapy including hormonal, biologic, targeted, and/or cytotoxic chemotherapy. Understandably, numerous patients recruited under surgery and/or radiation will receive systemic therapy as part of combined modality therapy, which is permissible. Regardless, all details regarding cancer diagnosis, stage, and treatment will be collected from the EMR, which will be detailed in the informed consent document.
 2. Any patient in follow-up by their primary oncology care provider and/or AYA and cardio-oncology survivorship clinic(s).
- All patients must be treated within the MHCCN thus ensuring access to clinical data in our system-wide EMR (Epic).
- Patients must obtain their cannabis either from a medical-use store, adult-use (recreational) store or both. Patients must obtain cannabis ONLY from medical/recreational stores. Illicit (or homegrown) sources are strictly prohibited.

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Key Information About this Research Study

Why is this study being done? This study is being done because there is a significant lack of data on the use of cannabis amongst cancer patients. We believe that the collection of this data will help researchers and clinicians better understand the needs and the impact of cannabis use in this specific patient population.

Why are you being asked to be in this research study? You are being asked to take part in this study because you are an oncology patient, receiving active therapy or in follow up following active therapy, and treated within the MaineHealth Cancer Care Network (MHCCN).

How many people will take part in this study and how long will it take? This study will include approximately 45 study participants within MaineHealth/MHCCN.

How long will you be in the study and how much time will it take up?

We expect that you will be in the study for 6 full months and will include an Enrollment/Baseline Visit and Monthly visits thereafter. The first visit will last for approximately 2 hours. All other visits will last for about 30 minutes. All visits will be done remotely or via phone.

What will you be asked to do? If you agree to be in this study, you will be asked to:

- Sign up for an app ([Releaf App | Cannabis Treatment Tracking & Research](#)) and complete journal entries about your cannabis use
- Receive weekly text or e-mail reminders to use Releaf App
- Receive monthly remote or phone check-ins from study team. There is also a baseline visit in which you will complete surveys with a study coordinator regarding your use of cannabis (including beliefs, medical guidance, benefits, side effects, etc.)
- Agree to obtain your cannabis only from storefront locations (illicit or homegrown cannabis is not allowed)
- Allow researchers to collect contact and demographic information, such as:
 - Name, Phone Number, Email
 - Address (to receive patient incentive gift cards)
 - Date of Birth
 - Veteran Status
 - Zip Code of your Residence
 - Level of Education
- Allow researchers to access your medical record to obtain information regarding your cancer diagnosis, stage, and treatments, such as:
 - Date of Cancer Diagnosis
 - Cancer/Tumor Type
 - Stage of Cancer
 - Cancer Treatment

- Cancer Status (i.e. active therapy, survivor, AYA)

What are the risks or discomforts that are possible from being in this study?

The risks involved with participation in this study are considered minimal and may include risks such as loss of confidentiality of data, stress from answering multiple and/or sensitive questions. You may skip a question or stop participation at any time. We will protect your confidentiality by ensuring that we use a secure, password-protected, logins that only members of the study team will have access to.

What benefits to you are possible if you participate in this study? The possible benefits you may experience by being in this research are having a better, and more clear, understanding of the frequency, type, and benefits and side effects, of your cannabis use. This applies to all participants as well and the general knowledge that may be gained with this study. Alternatively, there may be no direct benefit to you and/or other study participants.

If you say no to being in this study, do you have other options for your condition? Your medical care will not be impacted whether you decide to participate in this study or not. If you have questions, please talk to your regular doctor about these and other options that might be available to you.

Will being in this study cost you anything?

You or your insurance company will not be charged for your involvement in this research study (only the tests or services that are clinically indicated and/or are part of your standard treatment). You will still be responsible for the cost of your usual ongoing medical care, including procedures, non-study medications, and tests that your study doctor or regular doctor requires during this study as part of your usual medical care

Will you be paid for being in this study?

You will receive a small reimbursement for your time to complete surveys at baseline and monthly intervals (check-ins) for 6 months. This payment is administered in the form of gift cards per survey over the course of the study (for a maximum of \$75).

To learn more about this study, please e-mail:
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