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Monitoring Opioid Use in Cancer Survivors: Implementation of Screening, Brief Intervention, and Referral to Treatment (SBIRT) in a Clinical Setting

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MONITORING OPIOID USE IN CANCER SURVIVORS:
Implementation of Screening, Brief Intervention, and Referral to Treatment (SBIRT) in a Clinical Setting

CAPSTONE PROJECT PAPER

A paper submitted in partial fulfillment of the
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ABSTRACT

Kentucky is a disparate state, ranking as one of the top states in incidence, prevalence, and mortality for both opioid use disorders (OUD) and cancer. Due to the high volume of both diseases in the state, there is a rising concern about the overlap of these two populations. Cancer and its' treatment are known to cause chronic pain, defined as daily pain lasting 3 months or longer. Generally, chronic pain patients of any type are known to experience higher rates of opioid misuse (21-28%) and opioid dependence (8-12%) than the general population (4.1%, 0.9% respectively). The risk of OUD must be considered when initiating long-term opioid treatment for chronic pain, since a substance use disorder may result in poor pain control, dysimmune effects, and tumor proliferative effects.

This program will utilize a transdisciplinary team approach to implement Screening, Brief Intervention, and Referral to Treatment (SBIRT) at the University of Kentucky Markey Cancer Center (UK MCC) in Lexington, KY to assess cancer survivors' risk for developing OUD, monitor opioid use during the first 12-months of survivorship, and refer patients to alternative therapies to reduce reliance on opioids and improve pain management. The implementation of the program will be evaluated with a process evaluation and an outcome evaluation. Process evaluation metrics for the provider include: performance on trainings; administration of assessments, opioid monitoring measures, and pain scales; and rate of opioid prescriptions. Outcome evaluation metrics for the participant include: ability to manage pain; satisfaction with pain treatment plans; rate of completed referrals to specialists; change in OUD monitoring measure scores and number completed; and rate of opioid prescriptions. The program will utilize existing resources through UK Healthcare, the MCC Affiliate Network, and the MCC Research Network to implement the program to scale and disseminate findings across the state and to stakeholders.

TARGET POPULATION AND NEED

In the early 1990s, pharmaceutical companies claimed that opioids were not addictive and assured medical providers and patients that they were safe to be prescribed with minimal supervision. By 2015, the United States saw dramatic increases in prescription opioid abuse, black market sales, and deaths, leading to intensive restrictions for opioid prescribing.[1] Prescription opioids include oxycodone, hydrocodone, codeine, morphine, and many others, which proved to be far more addictive than pharmaceutical companies originally claimed.[2] The restricted access to prescription opioids had unintended consequences: people who could no longer have their opioid prescriptions filled began to transition to illegal opioids, like heroin, that were often laced with highly-potent synthetic opioids, such as fentanyl. By 2017, overdose and mortality rates skyrocketed and the U.S. Department of Health and Human Services department declared the opioid epidemic as a national public health emergency. In 2018, an estimated 130 people died every day from opioid-related drug overdoses.[1]

While mortality rates are shocking, misuse of prescription opioids is substantially more common. In 2018, the Substance Abuse and Mental Health Services Administration (SAMSHA) found that across the United States, 9.6 million adults aged 18 or older misused prescription opioid pain relievers in the past year, representing approximately 5.6% of young adults aged 18-25 and 3.6% of adults aged 26 or older. An estimated 1.5 million adults misused prescription pain relievers for the first time in 2018, meaning that approximately 4,400 adults misuse opioids for the first time every day.[3]

In addition to the opioid epidemic, the United States has also experienced devastating rates of cancer. As of 2017, cancer was the second leading cause of death with 599,108 cases, following closely behind heart disease, with 647,457 cases.[4] On a national level, as of January

2019, there were approximately 16.9 million cancer survivors living in the United States, representing 5.0% of the US population. The number of cancer survivors in the US is expected to increase to 21.7 million people by 2029, and to 26.1 million people by 2040.[5] The most common cancer sites among survivors includes female breast (23%, 3.6 million), prostate (21%, 3.3 million), colorectal (9%, 1.5 million), gynecologic (8%, 1.3 million) and melanoma (8%, 1.2 million).[6,7]

Cancer and its' treatment are known to cause chronic pain, defined as having pain every day for more than 3 months.[8] Cancer itself can cause pain in the body, typically from a tumor pressing on nerves, bones, or organs. Cancer screening and treatments can also cause pain, such as surgical pain from having a biopsy or tumor removed, or phantom pain after a body part has been amputated. Chemotherapy can cause peripheral neuropathy, a set of painful symptoms such as tingling or burning caused by damage to nerves, and gastrointestinal problems, such as mouth and throat sores that make it painful to eat, drink, or talk. Lastly, radiation treatments also cause pain, such as skin burns, scarring, and sores.[9] Patients deserve to have their pain treated, and to live a life as pain-free as possible.[9]

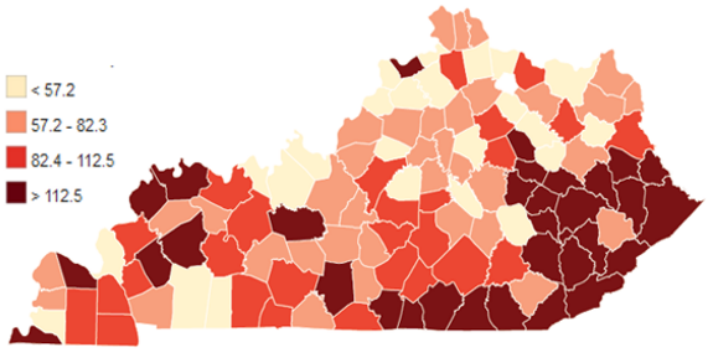
In light of the opioid epidemic, there has been investigation of opioid misuse in patients with chronic pain in general, since the risk of substance use disorder must be considered when initiating long-term opioid treatment.[10] In 2012, the National Health Interview Survey (NHIS) found that a total of 126 million adults (55.7%) reported some type of pain the last six months, with nearly 40 million adults (17.6%) experience severe pain, and approximately 25.3 million adults (11.2%) experience chronic pain.[11] As seen in *Table 1,* in 2015, a systematic review of 38 studies found that the rates of opioid misuse in chronic pain patients averaged between 21%-28% (range 95% CI: 13%-38%) and rates of substance use disorder to opioids averaged between 8%

and 12% (range, 95% CI: 3%-17%).[12],[13] More information on how the Diagnostic Statistical Manuals (DSM) have defined misuse versus dependence can be found in Appendix A.

Table 1. Comparison of Opioid Misuse/Dependence in Chronic Pain Patients and US General Population		
	Opioid Misuse	**Opioid Dependence Disorder**
Chronic pain patients	21-28%	8-12%
General population	4.1%	0.9%

Kentucky is one of the United States' leaders in the opioid epidemic,[14] and will be the catchment area for this proposal. According to 2019 Census data, there are approximately 4.5 million people living in the state. The state is 87.6% white alone, 8.4% Black or African American alone, and 4% represent American Indian and Alaskan Natives, Asian, Native Hawaiian and other islanders, and those with two or more races. 3.8% of the population identify as Hispanic or Latino. The median household income from 2014-2018 was $48,392, with the per capita income standing at $26,948 – nearly 17% of the state lives in poverty.[15]

In 2017, Kentucky providers wrote an average of 86.8 opioid prescriptions for every 100 persons as seen in *Figure 1*,[13] compared to the average US rate of 58.7 prescriptions.[16] According to the Centers for Disease Control (CDC), in 2017 Kentucky reported 1,160 deaths related to opioids, representing a mortality rate of 27.9 deaths per 100,000 persons, compared to the national average of 14.6 deaths per 100,000 persons.[16] Given the significantly higher rates of opioid prescribing and opioid deaths in the state, it would be reasonable to consider that the rate of



Source: Centers for Disease Control and Prevention, U.S. County Opioid Prescribing Rates, 2017

Figure 1. **Kentucky Opioid Prescribing Rates per 100 Persons, by County in 2017**

opioid misuse is likely higher than the national average.

As one of the most disparate states in the US, Kentucky has also experienced disproportionate cancer burden. Kentucky has consistently ranked as one of the highest cancer incidence and mortality rates of in the country, and currently holds the #1 spot with an average of 520.9 cases per 100,000 people annually between 2012-2016 (see *Table 2*).[17,18] Since the inception of the Kentucky Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute (NCI) in 1995 to the most recent data in 2017, there were 233,527 cases of cancer identified in Kentucky that are still living.[19]

Table 2. 2016 Age-Adjusted Cancer Rates: Incidence, Mortality, and Survivorship in Kentucky and the United States

	Cancer Incidence	**Cancer Mortality**
Kentucky	520.9 cases per 100,000 people	234.9 cases per 100,000 people
United States	448.0 cases per 100,000 people	189.8 cases per 100,000 people

Kentucky is well-positioned to be pioneers in ensuring that cancer survivors are having their pain treated in the best way possible, with minimal risk of opioid misuse or developing an opioid use disorder (OUD). A substance use disorder may result in poor pain control, and there is evidence that opioids can cause dysimmune effects, such as increased inflammation, decreased strength of the immune system and lower white blood cell counts, and tumor proliferative effects, meaning an increase in the number of cells as a result of cell growth and cell division.[10,20] In 2019, the University of Kentucky Markey Cancer Center (UK MCC) conducted a Community Needs Assessment (currently unpublished) among its patients and caregivers to identify barriers to treatment. At the time of the submission of this grant, 13% of community survey respondents and 9% of patient survey respondents reported that they used opioid prescription medications just for the feeling, more than was prescribed, or were prescribed for someone else on a monthly basis or more frequently.

It is important for healthcare providers to take a transdisciplinary team approach to identify at-risk individuals and intervene with non-pharmacologic treatment methods to avoid opioid misuse and dependence. There is a large evidence base showing that opioid continuing education for healthcare professionals improves their ability to correctly prescribe & administer opioids to patients, while reducing readmission for pain related issues and reducing stigma surrounding those with opioid use disorder, and increasing providers participation in utilizing prescription drug monitoring programs.[21,22]

A study published in 2017 found that cancer survivors are 1.22 times more likely to have an active opioid prescription 10-years post-treatment.[23] To stem the epidemic in prescription opioid–related use among cancer survivors, the American Society of Clinical Oncology formed an expert panel to conduct a systematic review of medical literature to develop evidence-based guidelines on chronic pain management in cancer survivors. The guidelines included recommendations such as screening for pain at every encounter, screening for opioid misuse, utilizing physical functionality assessments to determine appropriate care, assessing the risks of physical adverse effects of opioids used for pain management,[24] and incorporating universal precautions to minimize abuse, substance use disorder, and adverse events related to opioids.[8] As of 2020, there has not been a specific initiative to address opioid use in the cancer community at Markey Cancer Center, ultimately leading to the development of this proposal.

The Substance Abuse and Mental Health Services Administration (SAMSHA) provides funding for Screening, Brief Intervention, and Referral to Treatment (SBIRT) training and implementation. SBIRT is the program that will be utilized in this proposal, defined by SAMSHA as “an evidence-based practice used to identify, reduce, and prevent problematic use, abuse, and dependence on alcohol and illicit drugs,” and is being expanded to include

prescription drugs.[25] Motivational interviewing is a cornerstone of SBIRT, and will be employed to encourage patients to lessen their reliance on opioids and utilize alternative therapies to improve their pain management.[25] More information can be found in the Program Approach.

From 2013-2016, SAMHSA funded Medical Professional Training programs at numerous locations across the United States, including Northern Kentucky University and for University of Kentucky Research. Since 2003, SAMHSA has awarded 32 SBIRT grants to states, territories and tribal organizations to enhance services for persons with, or at risk for, substance use disorders. Despite the overwhelming rates of opioid dependence and overdose death rates, Kentucky has not yet been awarded a state cooperative agreement for SBIRT.[26]

Regarding opioid monitoring resources currently available to the population, the University of Kentucky Division of Community Medicine in the Department of Family and Community Health established the Central Appalachia Inter-Professional Pain Education Collaborative (CAIPEC). The goal of CAIPEC is to improve the delivery of chronic pain management to the population of Central Appalachia through an evidence-based and inter-professional approach. CAIPEC was developed to work with practice-based research network clinics and had three main aims: provide quality improvement methods for delivery of clinic care, deliver statewide continuing education (CE) activities to address opioid use in patients with chronic pain, and develop a multimodal mechanism to disseminate project results to clinics and participating providers. The target audience of the program are healthcare professionals including: Physicians, Advanced Practice Registered Nurses, Physicians Assistants, Massage therapists, Physical therapists, and Behavioral Healthcare Professionals.[27] CAIPEC is closely tied to the UK Physical Therapy and the UK Interventional Pain Associates teams, providing referrals to both when appropriate.

CAIPEC also provides Chronic Pain Toolkit, a collection of resources and templates for clinics to adapt based on their specific needs, designed to empower healthcare professionals to make deliberate changes in their opiate prescribing practices.[27] The toolkit is organized into 4 major sections: 1) Transforming Your Clinic Process, includes an implementation workbook for the planning and implementation phases, such as worksheets, sample clinic workflows, etc.; 2) Education Links, such as suggested guidelines, educational materials, and PowerPoint slide sets; 3) Resources, a repository of various instruments, such as physical functionality assessments, screening tools, etc.; 4) Maintenance of Certification Part IV Resources, an opportunity for providers to get credit for certification completion.

While the CAIPEC program offers a wealth of information and resources, it has not been disseminated beyond the Family and Community Practice department. The original onset of the program randomly selected eight clinics from the consortium to implement the program. This program has shown to be effective, [28] and can likely be adapted to other clinic areas such as cancer-related pain.

Other resources available UK Markey Cancer Center's Integrative Medicine team, offering services such as massage therapy, music therapy, acupuncture, yoga, Jin Shin Jyutsu and others. Additionally, Markey hosts an exceptional Psych-Oncology team of ten social workers. Their team focuses on: counseling patients and families after a diagnosis, throughout treatment and beyond to help them manage the emotional and social challenges of living with and caring for someone with a complex disease; teaching patients how to change behaviors (quitting smoking, healthy lifestyle) to ensure the best possible outcome; connecting patients with the services and resources they need to manage practical aspects of living with cancer, including financial and nutrition counseling, transportation and housing assistance; and informing patients

about resources available to them at Markey. They are a natural bridge between the initiatives of the CAIPEC group and the aims of this proposal.

To address community outreach and dissemination, the SBIRT intervention could potentially be expanded to the Markey Cancer Center Research Network (MCCRN) for further evidence of validity and then implemented in all of the Markey Cancer Center Affiliate Network (MCCAN) sites as a standard clinic protocol. MCCRN is comprised of 7 research sites who are all part of the Markey Cancer Center Affiliate Network. MCCAN is comprised of 19 hospitals across the state of Kentucky and encompasses the entire catchment area of MCC.

PROGRAM APPROACH

The main goal for Screening, Brief Intervention, Referral to Treatment (SBIRT), is to improve community health by reducing the prevalence of adverse consequences of substance misuse, including OUD, through early intervention and, when needed, referral to treatment. SBIRT can be used as a preventative approach by targeting individuals with non-dependent substance use, and is an effective strategy to intervene prior to the need for more extensive or specialized treatment.[29]

To determine appropriate steps for cancer survivors and their pain management, our proposal is to implement a clinic change process to include the Screening, Brief Intervention, and Referral to Treatment intervention during cancer survivors' follow-up appointments. SBIRT is an evidence-based public health program sponsored by the US Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment (SAMHSA, CSAT) to "identify, reduce, and prevent problematic use, abuse, and dependence" on alcohol and tobacco, and is being expanded to illicit and prescription drugs.[25,30]

SBIRT begins with a rapid assessment of substance use, then utilizes motivational

interviewing techniques to assess a patient's stage of change, as described in the Transtheoretical Model of Change (pre-contemplation, contemplation, preparation, action, maintenance and termination), and then performs a brief intervention.[29,31] Motivational interviewing is a style of counseling that guides participants to realize their personal goals, and helps to resolve ambivalence that prevents them from reaching their goals by improving self-efficacy. The five principles of motivational interviewing include: 1) Express empathy through reflective listening; 2) Develop discrepancy between clients' goals or values and their current behavior; 3) Avoid argument and direct confrontation; 4) Adjust to client resistance rather than opposing it directly; 5) Support self-efficacy and optimism.[32] On an interpersonal level of the Socio-Ecological Model, the goal is to assist the patient in becoming more aware of their potentially problematic behaviors, motivate them to change, and then refer them to a specialist. [33,34]

The intervention will take place in three clinics at Markey Cancer Center that focus on the following cancers: breast, prostate, and melanoma/skin. These particular cancer types were chosen because they have over a 90% 5-year relative survival rate, and were three of the four most common cancer sites treated at Markey in 2018.[35,36] Due to the high patient volume in these clinics, the investigative team suspects there will more likely be a subset of the population with either a past history or future risk of opioid misuse or dependence. Clinic volume figures and sample size calculation can be found in Appendix C. We will assess future risk of dependence by having participants complete the Screener and Opioid Assessment for Patients with Pain (SOAPP) Version 1.0-14Q, and utilize the Current Opioid Misuse Measure (COMM) during follow-up appointments to assess misuse and determine need for a brief intervention.

Evidence Base of Screening, Brief Intervention, and Referral to Treatment (SBIRT)

In 1980, the World Health Organization made a call to the scientific world to improve

treatment and diagnosis of people with hazardous alcohol use. The initial program of Screening and Brief Intervention was developed at this time, and ultimately developing the Alcohol Use Disorders Identification Test (AUDIT), which is now the most widely used evidence-based alcohol screening test in the world. A decade later, the program was expanded to include the Referral to Treatment component and has been applied in various settings across the globe. SAMHSA funded three cross-site evaluations to provide an independent, systematic examination of its SBIRT programs to determine whether the grant program had achieved its intended outcomes. The evaluation included two cohorts of grant recipients, totaling 11 programs, and described in terms of the SBIRT service components, performance sites, providers, management structure/activities and patient/client characteristics. In 2004, SAMHSA investigated the first cohort of SBIRT grant awardees, with the second cohort's evaluation taking place in 2009. As of 2017, the third cross-site evaluation was underway for the grant awardees in 2013 and 2014. Overall, the evaluations found the program was effective in its' intended outcomes, which was consistent with previously published research.[37]

To further investigate the strength of the evidence-base of SBIRT, an overall review was conducted, analyzing six meta-analyses of randomized clinical trials and one systematic review on non-alcoholic alcohol drinkers. The review reported that 5 of 7 studies found a moderate decrease in consumption, and 4 of 7 studies experienced a significant decrease in the number of participants who continued to use alcohol. The review also determined that a brief 15-minute intervention at multiple points of manifests lasting effects that persist for at least 6 months.[38] This supports SBIRT's claim that the program is effective in preventing problematic use, and is not only for those who have already developed a substance use disorder.

SBIRT is effective in a wide range of settings including emergency rooms, primary care

clinics, and community settings. Additionally, the SBIRT framework is valid to use for adolescents, adults, and seniors. The screening component has found to be effective in a variety of modalities including telephone, paper, online, and physician administered. The flexibility and validity of this framework for tobacco and alcohol use in various settings, populations, and modalities gives strong support for the success of employing this method for prescription medications, such as opioids.[34] Additionally, motivational interviewing has been found to be effective in chronic pain populations wishing to taper their opioid dose.[39]

In March of 2019, several medical doctors at Yale University conducted a randomized controlled trial using an adapted SBIRT-Pain Module (SBIRT-PM) that they had created to effectively screen for substance use disorders in veterans with chronic pain stemming from musculoskeletal disorders. The trial had three arms at a 2:1:1 randomization ratio: SBIRT-PM with counselling, Pain Module counseling only, or standard of care without counselling. Those who were randomized to the counselling conditions were significantly more likely to fulfill service referrals and make changes to their pain management plan. Participants in SBIRT-PM were significantly less likely to use substances over time ($\beta = -0.13$, $P = 0.015$, $d = -0.84$). The standard of care group were more likely to withdrawal from the study at week 12 (32% vs 12% and 11%, respectively; $P < 0.05$). Ultimately, SBIRT-PM showed promise as a way to engage veterans in pain treatment and reduce substance use, and provides evidence that SBIRT can effectively be used in a chronic pain population.[40]

Adaptations

SBIRT has been shown to be effective in a variety of settings but have primarily focused on tobacco and alcohol use, and has limited its focus to non-cancer pain populations. The first major adaptation in this intervention is using SBIRT in a cancer survivorship population with

cancer-related pain, who may also experience chronic pain. The second major adaptation to this intervention is using SBIRT for prescription opioid dependence. Currently, the effectiveness of SBIRT in cancer pain populations or in populations with prescription opioid dependence are unknown. Minor adaptations include using screening tools that will be used to assess need for risk monitoring and for assessment of opioid misuse, abuse, and dependence. The major adaptations of this intervention are essential to addressing opioid dependence in cancer survivors. In light of the opioid epidemic, it is now more important than ever to ensure that oncologists are confident in their opioid prescribing practices for their patients, and that patients are satisfied with their pain management treatment course. Anecdotal evidence shows that providers are already using SBIRT and motivational interviewing techniques to address opioid use in cancer patients. To date, there have not been any studies targeting this vulnerable population specifically with the SBIRT methodology.

Education, Stigma Reduction, Claims

There are major challenges regarding stigma reduction towards people who have cancer, people who receive opioid prescriptions, and those who have or are at risk of developing an OUD. It is important to remember that the goal of this program is to improve the cancer survivorship experience by identifying whether individual patients are best served by opioids for managing their pain; not to unnecessarily take away their medications. There are some cancer survivors who will have severe chronic pain for the rest of their lives and may need to be on some level of opioids during that time.[41,42] Cancer patients experience substantial pain from their treatments, and deserve to have that pain treated without feeling as though their provider or clinic staff is judging them for continuing to take opioid prescriptions. On the other side of the lens, providers understand how painful cancer can be, so they may not be concerned about a cancer

patient's opioid prescriptions, and be unaware of whether opioids may be inciting more harm than help.

There is strong evidence that educational anti-stigma interventions are successful in reducing stigma.[21,22,43] Our education plans for the clinic providers and staff regarding cancer pain will include the full spectrum of cancer treatment side effects, their correlation with pain, and appropriate pain management plans. To reduce stigma related to opioids, our education plans will focus on the neurological and physiological changes that happen after taking opioids for an extended period of time. This is essential for clinic staff to understand the underlying mechanisms that drive resistance to opioid reduction and cessation. By educating the clinic staff in this aspect, it will help them to understand from a biological level what is happening with their patients, and that it is not merely a moral failing or lack of motivation. Lastly, we will build providers confidence in their ability to prescribe the appropriate amount of opioids to their patients without needing to worry about contributing to the opioid epidemic.

Sustainability

This intervention is intended to be a clinic process change. We are intentionally designing this project to have the clinic staff provide and score the initial risk monitoring tool (SOAPP) to the participant, and then informing the provider of their score and whether they qualify for a brief intervention, rather than assigning these tasks to behavioral research associates whom will no longer be involved in the process after the grant ends. While there are still areas that can fail post-project period, our intention is that the screening mechanisms will become standard operating procedures embedded into the clinic workflow beyond the funding cycle of the grant. Our activities of providing the training to conduct the FMEA, intensive training with PDSA-cycle worksheets, and implementing the practice management specialist support this aim.

Additionally, the clinic champions will also receive motivational interviewing training to help them navigate resistance within the clinic staff and hold providers accountable to their training.

If our program is found to be implemented appropriately, as determined by the process evaluation and the outcome evaluation, the data from this project will allow the institution to secure funding from SAMSHA to provide an expanded, formal SBIRT training program for providers. Securing additional funding will further disseminate SBIRT implementation, resulting in an overall cultural change in the institution. We will communicate our study results via the MCCAN and MCCRN networks, UK Healthcare, and to the CAG, partners, and stakeholders through roundtable discussions, presentations, conference attendance, and others as deemed appropriate.

Inclusivity and Appropriateness for the Population

To ensure that all program materials are medically accurate, inclusive, and culturally and linguistically appropriate, we will use nationally recognized evidence-based guidelines and educational materials from the CAIPEC resources. We will submit materials that will be viewed by our participants to the Human Development Institute (HDI) at the University of Kentucky to assist in identifying any needed modifications. The Human Development Institute's website states that their mission is, "To promote the inclusion, independence, and contributions of people with disabilities and their families throughout the lifespan. We achieve our mission through education, research and evaluation, information sharing, leadership, and advocacy across Kentucky and the nation."[44] As a final reviewing team, we will employ our Community Advisory Group to review all materials to ensure that our material messages will be received in the way that they are intended.

To address any concerns the participants may have during their participation, we will supply several avenues for them to submit claims. The University of Kentucky Office of Research Integrity website states that, "It is IRB policy that a safe confidential, and reliable channel for current, prospective, or past research participants, their representatives or others, is provided that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol. Each IRB approved informed consent document includes the ORI Research Compliance Officer's toll-free phone number (1-866-400-9428) as a subject's primary contact point for this purpose."[45] Additionally, they will be given contact information for the primary investigators and research coordinator to submit concerns and claims. Lastly, the research staff will directly address the potential for these issues by directly asking participants at the end of their participation whether they had any concerns about their participation.

Recruitment and Retention

For an effective intervention, we will need to have a recruitment and retention plan for both the clinics and the patient participants. Clinic recruitment and retention is essential to the success of this intervention and requires a champion to ensure that the intervention is maintained in the workflow. Potential clinic champions and physicians have been recruited by utilizing a mutual acquaintance in the cancer center to establish an interpersonal relationship. The research team met with each clinic team to explain the purpose of the study and why their particular clinic was chosen as a potential participant. Clinic champions and physicians will be monetarily compensated for their time at an appropriate rate to ensure that they are satisfied with the additional steps in the clinic workflow. To encourage clinic retention, the clinics will have

monthly challenge rewards for those who completed the most screenings and had the most successfully completed referrals.

To recruit participants, study personnel will conduct the screening of potential participants, and inform the clinic staff of which people should be approached. The clinic staff will insert the research study consent form into their intake packet, to be reviewed while they are waiting for their appointment. Study personnel will review the study protocol, including referral to treatment options, and consent form with the patient. If willing to participate, the study personnel will obtain a signed informed consent and provide a copy to the participant. Compensation for the participants' time will include an initial $5 for completing the initial risk monitoring survey, provided to the participants and scored by the clinic staff, who will then inform both the study personnel and clinic provider on whether they are mild, moderate, or severe risk for dependence. To retain participants, the follow-up surveys will be completed during their regularly scheduled follow-up appointments. To compensate for their time, participants will receive $5 for each follow-up survey completed, totaling $15. If the participant completes all three follow-up surveys, the will receive an additional $15 at the completion of the study participation. This type of payment schedule is an acceptable standard in substance use populations for maximum retention, and the payment amounts are deemed low enough to prevent unintended coercion.

Since our target population is very specific and medically frail, we expect to have some difficulty with recruitment into the study. To assist in determining what changes need to be made in our recruitment strategy, we will ask eligible participants why they declined or agreed to participate. We will provide a set of responses in checklist format with an option for "other" to reduce burden on those who agree to answer. The responses will be determined by the focus

group prior to the beginning of the study and modified based on frequent fill-in responses from the “other” category.

Monitoring and Fidelity

Please see the Process Evaluation section of this proposal provides detailed information on how the sites will be monitored. To ensure fidelity and loyalty to the proposal, we are providing a $20,000 clinic stipend to increase buy-in from the staff by providing protected time for them to conduct the study. We will also identify a champion in each of the three clinics who will enthusiastically commit to the protocol and purpose of the study.

A 6-month readiness period for the implementation of the study will be employed to allow for an adjustment period. The readiness period will give the clinics an opportunity to get comfortable with motivational interviewing techniques before deploying in the research setting. During the first three months of the readiness period, providers and clinic champions will be trained in motivational interviewing techniques using resources provided by SAMSHA. “A Tour Motivational Interviewing: An Interprofessional Road Map for Behavior Change” is a free, self-paced online course provided by SAMSHA, and was prepared by the University of Missouri Kansas City School of Nursing and Health Studies’ Mid-America Addiction Technology Transfer Center.[46] Additionally, they will be provided with an "MI Reminder Card (Am I Doing This Right?),” a pocket card reference guide to take with them in the clinic. The 11 questions on this card assist in building self-awareness about the interventionists’ attitudes, thoughts, and communication style as they work.[46] The providers and champions will give a mock motivational interviewing intervention with a non-trained clinic staff worker each month. Both the clinic staff worker and the trainee will be given a case scenario for the ‘patient’ to act out. The mock intervention will be video recorded in order to reduce the Hawthorne Effect, and then observed

and scored by the Oncology Social Work trainer, who will grade the interaction based on the training manual standards. The trainee will be asked to view their interaction and grade themselves, then a meeting will take place to identify areas of improvement and conduct refresher training. Please refer to the Process Evaluation section for metrics that will be measured.

Challenges and Risks

Clinic-based research studies, such as this proposal, face unique challenges due to the setting. The most difficult challenge is that medical clinics are already exceptionally busy, severely limiting available time to identify eligible participants and conduct research. We will employ a Practice Management Specialist to find time savings in the clinic, as well as a Clinic Task Force to help ensure that the participant and provider have enough time in the clinic to complete the study materials, and maintain the integrity of the protocol as written within the clinic workflow. We will also provide a clinic stipend as an incentive for the clinics to assist in holding themselves accountable to maintain the research project. Buy-in from providers and clinic staff is essential to the success of this project. Another major challenge is that our providers cannot be blinded to the intervention, meaning that they may unintentionally bias results. Additionally, the providers may begin using the techniques and screening measures they've acquired during the study when interacting with other patients who are not enrolled.

The risks for patients to participate in this study are minimal and do not exceed the risks encountered in everyday life. Some questions on the study measures may be of sensitive nature and uncomfortable for some participants to answer. All participant contribution is voluntary, participants are allowed to skip any questions that they do not want to answer and can discontinue their participation at any time. Patient materials will be de-identified and coded with

a unique participant code and will follow the UK Standard Operating Procedures to maintain HIPAA compliance and Good Clinical Practice guidelines.

PERFORMANCE MEASURES AND EVALUATION

This proposal will use a stepped-wedge study design, also known as a phased implementation, with each clinic serving as its own control. To measure whether the intervention is effective and not due to external factors, we will compare baseline counts for the outcome measures versus post-implementation counts. We will "Go-Live" in Clinic 1 during Year 1, month 7; Clinic 2 in month 9; and Clinic 3 in month 11. This will provide two months of data collection in each clinic, and an opportunity to improve the intervention before deploying in the next clinic. This timeframe also allows to have two months of implementation in Clinic 3 before the beginning of Year 2 of the project. This design is ideal from an ethical standpoint: this is a high-risk population and it is imperative that all eligible participants receive the intervention. More information on Study Design, Eligibility, and Sample Size can be found in Appendix C.

The first measure we will administer to participants is the Screener and Opioid Assessment for Patients with Pain (SOAPP) Version 1.0-14Q and is meant to be completed before a patient is placed on a long-term opioid therapy, when a pain management plan is established.[47] See Appendix D for full instrument, and *Table 3* for cutoff score information. This tool is designed to assist clinicians in determining how much monitoring a patient on long-term opioid therapy will likely require and takes approximately 8 minutes to complete. It is essential to ensure that cancer survivors have adequate chronic pain management because all people deserve to be as pain-free as possible. In light of the opioid crisis, many practitioners are hesitant to prescribe opioids,[42] and this tool helps to clarify concerns.

One important, yet often overlooked, aspect of the COMM tool is that it addresses family

history of substance abuse and whether the patient has ever had their medications lost or stolen, which can be an indicator to educate patients on proper opioid storage at home.[48] This item is imperative because in Kentucky, of those who use prescription opioids non-medically for more than 200 days per year, 27% use their own prescriptions; 26% are given them by friends or relatives; 23% buy opioids from friends or relatives; and only 15% buy from a drug dealer.[49] Since the prescribing rates in the south eastern and south western parts of KY are much higher than the central part of the state, our research team and providers will need to be proactive in addressing shared prescriptions. If a participant from a high-risk area indicates that they have had prescriptions lost or stolen, or friends or family with substance abuse disorders, our providers will take special care to address this during the motivational interviewing intervention.

Table 3. SOAPP and COMM Cutoff Scores

	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio
SOAPP						
Score 7 or above	.91	.69	.71	.90	2.92	.13
Score 8 or above	.86	.73	.75	.86	3.19	.19
Score 9 or above	.77	.80	.77	.80	3.90	.28
COMM						
Score 9 or above	.77	.66	.66	.95	2.26	.35

The second measure we will administer to participants is the Current Opioid Misuse Measure (COMM), a 17-item self-report instrument designed to monitor a chronic pain patient's use of opioids and assess misuse by asking about social, emotional, and functional problems and behaviors related to prescription medication misuse.[50] See Appendix E for full instrument. The COMM will be administered during the 3 month, 6 month and 12 month follow-up appointments. Follow-up timelines vary dramatically depending on the type of cancer, location, and treatments (radiation, chemotherapy, surgery), however it is standard at minimum to have a 3, 6, and 12 month follow-up appointment. Regarding the construct validity of the instrument,

Meltzer et al. found higher COMM scores in patients with chronic pain who had a prescription drug use disorder than in those who did not have the disorder.[51] *Table 4* below shows the psychometric properties associated with our validated measures, including the Opioid Therapy Provider Survey (OTS), which is used in the Process Evaluation.

Table 4. Validity of Measures	
Construct	Psychometric Properties
Prediction of Need for Opioid Risk Monitoring	Screener and Opioid Assessment for Patients with Pain (SOAPP) Version 1.0-14Q. The 14-item survey is scored on a 5-point Likert scale. Chronbach's alpha was calculated for initial SOAPP results (N=175) and for follow-up retest (N=95), achieving a=0.74 for both samples.[47] Negative Predictive Value for a cutoff score of 7 is .90; score of 8 is 0.86, and score of 9 is 0.80. Despite its' intention to capture as many people as possible, leading to many false positives, a person with a positive SOAPP score at the cutoff of 7 is 2.94 times as likely to be someone who is actually at high risk; scores of 8 are 3.19 times as likely; scores of 9 are 3.90 times as likely.
Opioid Misuse Assessment	Current Opioid Misuse Measure (COMM). This tool is intentionally designed to over-identify misuse, rather than failing to identify those at high risk (PPV = 0.66, NPV = 0.95). A study published in the Clinical Journal of Pain examined the validity and reliability of the COMM against the Aberrant Drug Behavior Index (ADBI), finding the internal consistency for cross validation to be excellent with a = 0.83, compared to a = 0.86 in the original study. The receiver operating characteristic curve (ROC) analysis yielded an area under the ROC (AUC) of 0.79 (Standard error = .031; 95% CI: .74 to 86; $p < .001$).[50]
Pain Levels	FACES Pain Scale. A study comparing four pain scales in children ages 3-18 found the FACES Pain Scale to be valid and reliable: a = .60, r = .74. There were no significant differences in validity or reliability across all four measures.
Provider confidence in prescribing opioids	Opioid Therapy Provider Survey (OTS). The 10-item survey is scored on a 5-point Likert scale, where 1= strongly agree and 5= strongly disagree.[52] All items were based on an extensive literature review, then developed through consensus among researchers with over 20 years averaged experience with chronic pain patients. Content validity was initially established through item examination for missing data and respondent comments and reliability was judged to be suitable (Cronbach's alpha = 0.28).[53]

Both the SOAPP and COMM measures take less than 10-minutes to complete and are self-reported, making it practical for the patient to complete during their clinic visits without significant disruption of the clinic workflow. Additionally, both measures use the same scoring methods, by summing the individual question scores to calculate the overall total score. Using similar scoring mechanisms will reduce the need for additional training.

Patient satisfaction and ability to manage pain will be measured by using a self-report survey at each encounter, as seen in *Tables 5*. These items will be developed with assistance from the Behavioral Research Assistant.

Table 5. Patient Perspective Measures		
Property	Verbiage	Scoring
Patient Satisfaction	"How satisfied are you with your pain treatment?"	5-point Likert scale (1 = Extremely Dissatisfied to 5 = Extremely Satisfied)
Pain Management	"How well are you able to manage your pain?"	5-point Likert scale (1 = Extremely Dissatisfied to 5 = Extremely Satisfied)

To measure pain levels, we will use the Wong-Baker FACES Pain Rating Scale (0 = No Hurt, 10 = Hurts Worst) as seen in Figure 2.[54] Physical functionality will be measured using assessments provided in the CAIPEC toolkit.

Figure 2. Wong Baker FACES Pain Rating Scale[54]

Process Evaluation

The process evaluation for this program will be closely tied with the project management plan to ensure that we are implementing the project according to the project schedule and reaching the goals of the program. A Failure Modes and Effects Analysis (FMEA) will be conducted several times during the project by the Clinic Task Force, as seen in the Gantt Chart, specifically during the last 3 months of the readiness period (Year 1 Q2), during the first 6 months post-Go-Live (Year 1 Q3, Q4) and then at Year 2 Q1 and Q4. To conduct the FMEA, we will assess the following: 1) Steps in the process 2) Failure Modes (What could go wrong?) 3) Failure Causes (Why would the failure happen?) 4) Failure Effects (What would be the

consequences of each failure?).[55] We will use a team approach to modify the protocol to address the concerns. During the lifetime of the project, we will track the identified FMEA aspects during the project with our PDSA cycle worksheets. *Table 6* below outlines the process evaluation metrics that will measured to ensure proper provider education to support successful implementation and execution.

Table 6. Process Evaluation Metrics for Providers
1) Quiz scores on SBIRT and educational trainings including: a. Provider knowledge of guidelines for cancer pain patients and opioid prescribing b. Knowledge of palliative care alternative therapies for appropriate types of pain c. Confidence in prescribing opioids (OTS Survey)
2) Motivational interviewing performance
3) Number of physical functionality assessments completed
4) Number of opioid monitoring measures given
5) The number of referrals given for alternative therapies
6) Number of FACES pain scales administered
7) Rate of opioid prescriptions

The metrics for rate of opioids prescribed and number of referrals given and filled will be extracted from the Electronic Health Record. Physical functionality and FACES scale numbers will be inserted into the Electronic Health Record as well to improve sustainability and adherence to the protocol. To measure the providers' knowledge of guidelines for cancer pain patients and knowledge of alternative therapies for appropriate types of pain available at UK, we will conduct a pre-test prior to education and training during the readiness period. Since availability of therapies are location-specific, we will need to modify existing measures provided in the CAIPEC toolkit.

To identify key successes, challenges, and lessons learned, we will conduct key informant interviews every month with the providers, clinic staff, and project staff. The topics of conversation in the interviews will begin with reviewing the PDSA cycle worksheets and how they have aligned with the pre-project FMEA analysis. We will also review metrics that we have

collected during the project, specifically the recruitment strategies, recruitment numbers, number of referrals given and completed, counts of major and minor protocol deviations, patient satisfaction, etc. The interviews will allow the team to provide their input as executors of the protocol and study impact, while providing confidentiality. We have elected key informant interviews rather than focus groups to offset group-think about how well the intervention is working. Additionally, key informant interviews provide the opportunity to receive more detailed feedback about how the providers, clinic staff, and other project staff are performing and interacting with participants without risking fear of retaliation.

Outcome Evaluation

To assess the impact of the SBIRT intervention and determine the extent to which the outcome goals were met by the program and not due to chance or external factors, we will compare baseline metrics to post-implementation metrics. Output metrics for the participant are listed in *Table 7*.

Table 7. Outcome Metrics for Participants
1) Satisfaction with pain treatment
2) Ability to manage pain
3) Scores on opioid monitoring measures (SOAPP and COMM scales)
4) Number of opioid monitoring measures completed
5) Number of referrals to palliative care or alternative therapies completed by the patient.
6) Rate of opioid prescriptions

CAPACITY OF APPLICANT ORGANIZATION

The University of Kentucky is categorized as a Research Intensive Institution that has extensive experience in implementing evidence-based programs on a large scale, as well as implementing projects in the communities. Research and academic activity at the University of Kentucky (UK) spans all 16 colleges, the Graduate School (including the James W. Martin School of Public Policy and Administration and the Patterson School of Diplomacy and

International Commerce), some 80 multidisciplinary research centers, and 30 core research facilities. UK is one of 115 private and public universities in the country to be classified by the Carnegie Foundation for the Advancement of Teaching among Doctoral Universities: Very High Research Activity (R1) in 2018. R1 universities represent 2.5% of all institutions in the classification system. UK faculty, staff, and students brought in more than $417.1 million in new sponsored project awards in FY 2019. Of that total, UK was awarded $241.8 million in grants and contracts from federal agencies.

In regards to substance misuse and abuse, UK is home to the Center for Drug Abuse Research, which facilitates the largest research grant ever received by the University of Kentucky, NIH's HEALing (Helping End Addiction Long Term) Communities Study. The HEALing Communities Study is a four-year, $87 million study aimed at reducing opioid overdose deaths by 40 percent, and was developed by researchers from UK spanning six colleges, in partnership with state leaders. As one of four sites nationwide, UK and the Commonwealth of Kentucky will address the opioid epidemic in a randomized study that includes 16 Kentucky counties acutely impacted by opioid abuse. The study will leverage existing resources and initiatives, in partnership with communities, to implement strategies and set evidence-based standards that will become a national model for fighting the opioid epidemic.

As the only NCI-designated cancer center in Kentucky, MCC's mission is to reduce cancer mortality through a comprehensive program of cancer research, treatment, education, and community engagement with a particular focus on the underserved Appalachian population of eastern Kentucky. Since UK MCC is so robust, it hosts its' own business office to manage financial resources, interfacing closely with the main campus Accounts Payable and Payroll departments. According to the 2018 Annual Report, MCC is driven by 235 research projects

representing more than $41 million in research, with 2.7 million dedicated to education and research training. The MCC treats nearly 3,400 new cancer patients and over 8,000 returning cancer patients and survivors annually at the Chandler Medical Center.[36]

MCC has a substantial community partnerships across the state of Kentucky MCC's MCCAN and MCCRN sites extend into Appalachia and surrounding regions at 22 separate facilities with a shared vision of increased access and delivery of high-quality cancer care, and clinical trials. A new collaboration, UK Markey Cancer Center at Lexington Clinic will enhance and expand outpatient cancer care throughout Central Kentucky.

The University of Kentucky is home to extensive quality improvement initiatives, ranging from clinical care to research to administration. UK HealthCare delivers high-quality continuing professional development activities to physicians, pharmacists, and other health care professionals via the CECentral platform, which functions as a full-service continuing education (CE) solution for healthcare professionals. To manage staff performance, UK uses enterprise services for annual performance reviews, time entry, and paid leave.

The University of Kentucky is committed to a diverse and inclusive workforce that strives to foster a community where people regardless of sex, race, ethnicity, religion, age, ability, sexual orientation, or gender identity, can feel secure and welcome. In the interest of maintaining a safe and healthy environment for our students, employees, patients and visitors the University of Kentucky is a Tobacco & Drug Free campus. As an Equal Opportunity Employer, we strongly encourage veterans, individuals with disabilities, women, and all minorities to consider our employment opportunities.

PROJECT MANAGEMENT

The project management plan below describes how the project will be implemented,

managed, and monitored. See Appendix F for the Logic Model and Appendix G for the Gantt Chart, detailing activities during the 3 year project period, including plans for FMEA analysis and PDSA-cycle worksheets. Once the project reaches the "Go-Live" stage, we will use "Plan-Do-Study-Act" (PDSA) worksheets to delineate areas of improvement for our program, found in Appendix H. We will determine our initial approach and set a goal number for the appropriate activities, such as participant accrual. During the initial 3 months post-Go-Live, we will 'study' the approach and the accrued metrics on a bi-weekly basis before making minor changes for the second round of the PDSA cycle. A bi-weekly cycle schedule is ideal, since it is long enough to allow enough time for changes to gain traction but short enough to prevent major issues to go unnoticed. During months 5-12, we will continually assess the study progress to address significant changes that need to be made, such as changes in clinic workflow, refresher training for project staff, changes in data collection or management processes, participant recruitment and attrition, and others. By the end of year 1, we expect to have solidified and stabilized all aspects of the protocol to run smoothly through years 2 and 3. We plan to conduct interim statistical analysis every 6 months to monitor impact.

Project Management: Team Responsibilities

See Appendix I for the Organizational Chart, outlining personnel reporting lines.

Table 8. Project Management: Team Responsibilities

Title	Responsibilities
Primary Investigator	1) Provide consultation to clinics and act as final authority on workflow changes 2) Review high-level progress reports of the project to ensure milestones are being met in accordance with the funding sponsor's guidelines 3) Review potential participants' screening files and approve enrollment 4) Assist in hiring and termination of key staff 5) Act as the emergency contact for Adverse Events and Serious Adverse Events. 6) Disseminate findings to CAG, Partners, and Stakeholders.
Project Director	1) Develop, monitor, and make any necessary changes to the research protocol, budget, process evaluation, staff scheduling, IRB continuation review submissions, research participant payments, and other administrative activities as deemed necessary.

	2) Identify and interview key project staff. Supervise all project staff. Ensure proper trainings have been completed by all research staff, clinic personnel, and clinic providers. Assess professional development needs; provide at minimum annual professional development opportunities for research staff and semi-annual opportunities as deemed necessary. 3) Engage the Community Advisory Group 4) Report Adverse Events and Serious Adverse Events to the appropriate authorities on the appropriate timelines.
Clinic Providers	1) Central point of contact between participants and research team. 2) Conduct motivational interviewing techniques to improve likelihood that a participant will agree to reducing opioid prescriptions and follow through with referrals. 3) Provide referrals to alternative therapies for participants. 4) Provide brief report of interactions with participants to clinic staff, to be passed off to Behavioral Research Associates for documentation.
Oncology Social Workers	1) Provide sensitivity and motivational interviewing trainings to clinic providers. Track education and trainings for all clinic personnel and report to Project Director. 2) Assist in patient navigation to schedule their referral appointments, arranging transportation to/from the clinics, etc. 3) Coordinate with Behavioral Research Associates to ensure all participant materials and data are available and entered according to project timelines. 4) Act as mediator for tension between providers, clinic staff, and participants.
Behavioral Research Associates	1) Reviewing Electronic Medical Record data to identify eligible patients for recruitment 2) Approaching patients in the clinic to recruit into the study, completed all screening and consent procedures. Ensure protocol materials have been complete and returned by clinic staff. 3) Provide participant payments. 4) Review all data collection and ensure procedures have been followed according to Good Clinical Practice Guidelines. 5) Enter paper-based survey data. Conduct minor data management as needed. 6) Provide administrative services such as putting together materials for participant screening files, creating participant calendar schedules, tracking demographic metrics for IRB continuation review reporting, etc.
Biostatistician	1) Develop study design 2) Conduct sample size and power calculations 3) Conduct preliminary, intermediary, and final data analysis 4) Conduct major data management as needed 5) Provide data interpretation summaries and figures for presentations, publications, future grant proposals, etc.
Practice Management Specialist	1) Identify places in clinic workflow to find time-savings in order to insert research protocol without increasing required clinic time for the study. 2) Conduct the Failure Modes and Effects Analysis.
Clinic Task Force	1) Ensure proper implementation of the study into the clinic workflow to increase sustainability after the project grant funding ends. 2) Track progress of Failure Modes Effects Analysis and Plan, Do, Study, Act worksheets.

Clinic Staff	1) Coordinate with the behavioral research associates to ensure that identified participants who are potentially eligible for the study are screened, and if eligible, consented. 2) Distributed the SOAPP and COMM scales to the participants. 3) Score SOAPP and COMM scales, communicate to provider whether a brief intervention or referral to treatment is needed. 4) Provide completed SOAPP and COMM scales to the Behavioral Research Associates, along with all reports from the provider. 5) Contact Oncology Social Work team to assist with patient navigation.

PARTNERSHIPS AND COLLABORATION

Our stakeholders and partners are entities that are imperative to the successful implementation of the proposed project. We have identified groups from a national, state-wide, and the local community level to ensure comprehensive representation, seen in *Table 9*. We have obtained letters of support for all entities listed below. Effective two-way communication with stakeholders and partners is essential to the success of this project. Our Primary Investigator and Project Director will be the central points of contact for all communications. We will disseminate a quarterly newsletter to local entities, host bi-annual meetings with local and state entities, and provide a bi-annual report to local, state, and national level groups.

Table 9. Stakeholders and Community Partnerships

Entity	**Level**	**Role**
American College of Surgeons - Commission on Cancer	National	A consortium of professional organizations dedicated to improving survival and quality of life for cancer patients through standard setting, which promotes cancer prevention, research, education, and monitoring of comprehensive quality care.
American Society of Clinical Oncology	National	Diverse network of nearly 45,000 oncology professionals dedicated to providing the highest-quality resources in education, policy, the pioneering of clinical research, and advancing cancer care.
US Department of Health and Human Services	National	The largest biomedical research agencies in the world. Made of 27 Institutes and Centers, including the NIH, NIDA, NCI, and SAMHSA
Kentucky Injury Prevention and Research Center (KIPRC)	State	Partnership between UK and Kentucky Dept. for Public Health. Works to reduce injury through education, policy initiatives, public health programming, surveillance, risk factor analysis,

		direct interventions, and evaluation. Hosts findhelpnowky.org.
Kentucky All Schedule Prescription Electronic Reporting (KASPER)	State	Controlled substance prescription monitoring system, tracks prescriptions per person to assist medical personnel in decision-making.
Lexington Fayette Urban County Government and Health Department	Local	Performs essential functions such as providing police protection, administrating health and welfare services, keeping records, establishing policies and laws.
Local Lexington Hospitals: St. Joseph Health, Baptist Health, Lexington VA Medical Center, The Ridge Behavioral Health System, Eastern State Hospital	Local	Provide medical services to Kentucky residents. Stakeholders who have a vested interest in the opioid epidemic, cancer treatment, and quality improvement initiatives.
UK Office of the Vice President for Research	Research	Major research entity at UK; provides oversight and guidance of 13 multidisciplinary research centers, including MCC and CCTS
UK Center for Drug Abuse Research	Research	Conducts research into the biological, psychological, sociopolitical, and clinical aspects of substance abuse and related behavior. Provides consultations to public agencies and state and local government
UK College of Medicine	Clinical & Research	Provide medical services to Kentucky residents, ensuring best practices are being followed. Major drivers for implementation of new research findings. These entities are directly involved in this grant proposal and will be represented when disseminating findings to other groups.
UK Healthcare	Clinical	
UK Interventional Pain Associates	Clinical	
UK Healthcare Palliative Care Team	Clinical	

Community Advisory Group

We will establish a Community Advisory Group specifically regarding opioid misuse in cancer survivors. The Primary Investigator of this project has identified 7 main areas to obtain representation, and will host bi-annual meetings to discuss barriers to implementation, challenges with clinic work flow, recruitment and retention, and other challenges in addition to the communications with stakeholders and partners mentioned above. To recruit these individuals, the Primary Investigator will reach out to the organizations by prioritizing those of which they already have established connections. For those that do not have an established network, the PI

will directly contact the organizations to request a meeting consultation. All individuals will be compensated monetarily for their time on the CAG. The Community Advisory Group will ideally be comprised of individuals from the organizations in *Table 10*.

Table 10. Community Advisory Group		
Entity	***Personnel***	***Area of Representation***
Markey Cancer Center Affiliate Network	John Lennon, Director	Dissemination of programs across MCC; Cancer Survivor
Markey Cancer Center Patient Advisory Group	George Harrison	Cancer survivors and patients
UK Central Appalachian Inter-Professional Educational Collaborative (CAIPEC)	Hann Solo, Primary Investigator	Implementation of an opioid prevention program in the clinic
UK Helping to End Addiction Long-term (HEAL) Initiative	Leia Skywalker, Director	Implementation of an interventional opioid research program in the community
Voices of Hope	Paul McCartney, Co-founder	Community-based opioid treatment referral agency; Recovering opioid addict
Bluegrass Care Navigators	Obi Wan Kenobi, Registered Nurse,	External consultant for palliative care
Cardinal Hill Rehabilitation Center,	Ringo Starr, Director of Therapy Operations	External consultant for long-term rehabilitation
Kentucky Cabinet for Health and Family Services	Fred Rogers, Social Worker	Social Work
Human Development Institute, Health and Wellness Initiative	Bob Ross, Program Director	Disabled population
Lexington Fire & Emergency Services	Jason Momoa, Fire Marshal	First Responders for Ambulatory Services

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APPENDICES

Appendix A. DSM-IV-TR Diagnostic Categories for Substance Abuse and Substance Dependence	
Type	Definition
Nonmedical use	Use of prescription drugs that were not prescribed by a medical professional (i.e., obtained illicitly) or use for the experience or feeling a drug causes.
Misuse	Incorrect use of a medication by patients, including: use a drug for a purpose other than that for which it was prescribed; take too little or too much of a drug; take it too often; or take it for too long (misuse does not apply to off-label prescribing)
Abuse	A maladaptive pattern of substance use, leading to clinically significant impairment or distress as manifested by one or more behaviorally based criteria.
Physiological dependence	Increasing tolerance for a drug, withdrawal signs and symptoms when a drug is discontinued, or the continued use of a substance to avoid withdrawal.
Psychological dependence:	A set of psychological symptoms that demonstrate overall loss of control or obsessive-compulsive drug-seeking and continued use of a substance in spite of clearly adverse consequences. Symptoms may include specific physiological signs of dependence such as increasing tolerance or withdrawal signs and symptoms when the drug is discontinued.
Pseudoaddiction	Drug-seeking and other behavior that is consistent with addiction but actually results from inadequate pain relief. Once the pain is adequately treated, the person no longer abuses the medication

Appendix B. DSM-V Diagnostic Criteria for Substance Use Disorder
1. The substance is often taken in larger amounts or over a longer period than was intended.
2. There is a persistent desire or unsuccessful effort to cut down or control use of the substance.
3. A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects.
4. Craving, or a strong desire or urge to use the substance, occurs.
5. Recurrent use of the substance results in a failure to fulfill major role obligations at work, school, or home.
6. Use of the substance continues despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of its use.
7. Important social, occupational, or recreational activities are given up or reduced because of use of the substance.
8. Use of the substance is recurrent in situations in which it is physically hazardous.
9. Use of the substance is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
10. Tolerance, as defined by either of the following: a. A need for markedly increased amounts of the substance to achieve intoxication or desired effect. b. A markedly diminished effect with continued use of the same amount of the substance.
11. Withdrawal, as manifested by either of the following: a. The characteristic withdrawal syndrome for that substance (as specified in the DSM-5 for each substance). b. The use of a substance (or a closely related substance) to relieve or avoid withdrawal symptoms.

The Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision (DSM-IV-TR), provides diagnostic categories for substance abuse and substance dependence.[56] There are six definitions to consider, the program approach in this grant intends to screen for all possible scenarios listed in Appendix A. The DSM-V replaced the separate categories of substance abuse and substance dependence with a single category: substance use disorder (SUD).[56] The symptoms associated with an SUD fall into four major groupings: impaired control, social impairment, risky use, and includes the pharmacological criteria of tolerance and withdrawal. Depending on the substance, there are 10 or 11 criteria that can cause clinically significant impairment or distress, and must occur within a 12-month period. There are three sub classifications—mild, moderate, and severe – which are determined by the number of present diagnostic criteria.[57] Those who have two or three criteria are considered to have a "mild" disorder, four or five is considered "moderate," and six or more symptoms, "severe." The diagnostic criteria can be found in Appendix B.

Note that the terms 'Tolerance' and 'Withdrawal' are not used as diagnostic criteria for persons taking opioids prescribed for clinical care. Doctors expect that patients will experience some tolerance when placed on an opioid medication and may need an increased dosage, especially during active cancer treatment. They also expect withdrawal effects when reducing a pain medication, and will effectively taper down the dosage to reduce unpleasant symptoms. In these scenarios, the patient is not considered to have developed a substance use disorder unless at least three of the other criteria are present.[56]

Appendix C. Study Design, Eligibility, and Sample Size Calculation

Study Design and Eligibility

This proposal will use a stepped-wedge study design, also known as a phased implementation, with each clinic serving as its own control. Outcome metrics will be compared to baseline counts during the waiting period. This design is ideal from an ethical standpoint: this is a high-risk population and it is imperative that all eligible participants receive the intervention.

The inclusionary criteria are as broad as possible to replicate real-life scenarios. Eligible participants will include adults aged 18 and older who score as Moderate or High risk on the SOAPP scale. All eligible participants will be in complete remission and transitioning to a survivorship phase, and all stages of cancer and treatment types will be included. People with prior history of drug abuse and other pre-existing health conditions will also be included. If interested, the participant will be enrolled in the study screening procedures. Those with a score as moderate to high risk on the SOAPP opioid risk monitoring scale will be eligible to enroll in the study. Upon obtaining informed consent, the participant will receive the Screening, Brief Intervention, and Referral to Treatment intervention with motivational interviewing. Participants will then complete the COMM survey at the 3 month, 6 month, and 12 month follow-up appointments. More information about timeline specifications can be found in the Performance Measures and Evaluation section. To measure whether the intervention is effective and not due to external factors, we will compare baseline counts for the outcome measures (number of referrals, etc.) versus post-implementation counts. Specific details on the evaluation items we will measure can be found in the Outcome Evaluation section.

Sample Size Calculation

According to the Markey Cancer Center 2017 Annual Report, there were a total of 619 cases for breast (all sexes), prostate, and melanoma/skin cancers treated at MCC. These break out to 358 cases for breast, 153 cases for prostate, and 108 cases for melanoma/skin.

Effect sizes were estimated based on the literature of SBIRT, with a Cohen's *d* range from 0.17 to 1.35 within the interventional groups.[58] Conventional medium effect size is accepted at 0.5, with a large effect size accepted at 0.8. Based on the clinic volume of 619 patients treated last year for the specific disease sites, and the literature stating that 10% of cancer survivors were still being prescribed opioids 10 years past diagnosis, our initial assumption for the sample size would be around 100 people. To determine the appropriate sample size, and since we knew how many patients have historically been treated at the clinic, we conducted a sample size for percent frequency in a population as a random sample. With an effect size of 0.8, and anticipated percent frequency of OUD 10% in the population, we found that a sample size of 91 would be an acceptable target for recruitment. We expect to screen twice as many people as are eligible to participate, for a total of 300 people screened.

Appendix D. Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0 - 14Q

SOAPP® Version 1.0-14Q

Name: _____ Date: _____

The following are some questions given to all patients at the Pain Management Center who are on or being considered for opioids for their pain. Please answer each question as honestly as possible. This information is for our records and will remain confidential. Your answers alone will not determine your treatment. Thank you.

Please answer the questions below using the following scale:

0 = Never, 1 = Seldom, 2 = Sometimes, 3 = Often, 4 = Very Often

1. How often do you have mood swings?	0 1 2 3 4
2. How often do you smoke a cigarette within an hour after you wake up?	0 1 2 3 4
3. How often have any of your family members, including parents and grandparents, had a problem with alcohol or drugs?	0 1 2 3 4
4. How often have any of your close friends had a problem with alcohol or drugs?	0 1 2 3 4
5. How often have others suggested that you have a drug or alcohol problem?	0 1 2 3 4
6. How often have you attended an AA or NA meeting?	0 1 2 3 4
7. How often have you taken medication other than the way that it was prescribed?	0 1 2 3 4
8. How often have you been treated for an alcohol or drug problem?	0 1 2 3 4
9. How often have your medications been lost or stolen?	0 1 2 3 4
10. How often have others expressed concern over your use of medication?	0 1 2 3 4

Appendix E. Current Opioid Misuse Measure (COMM)

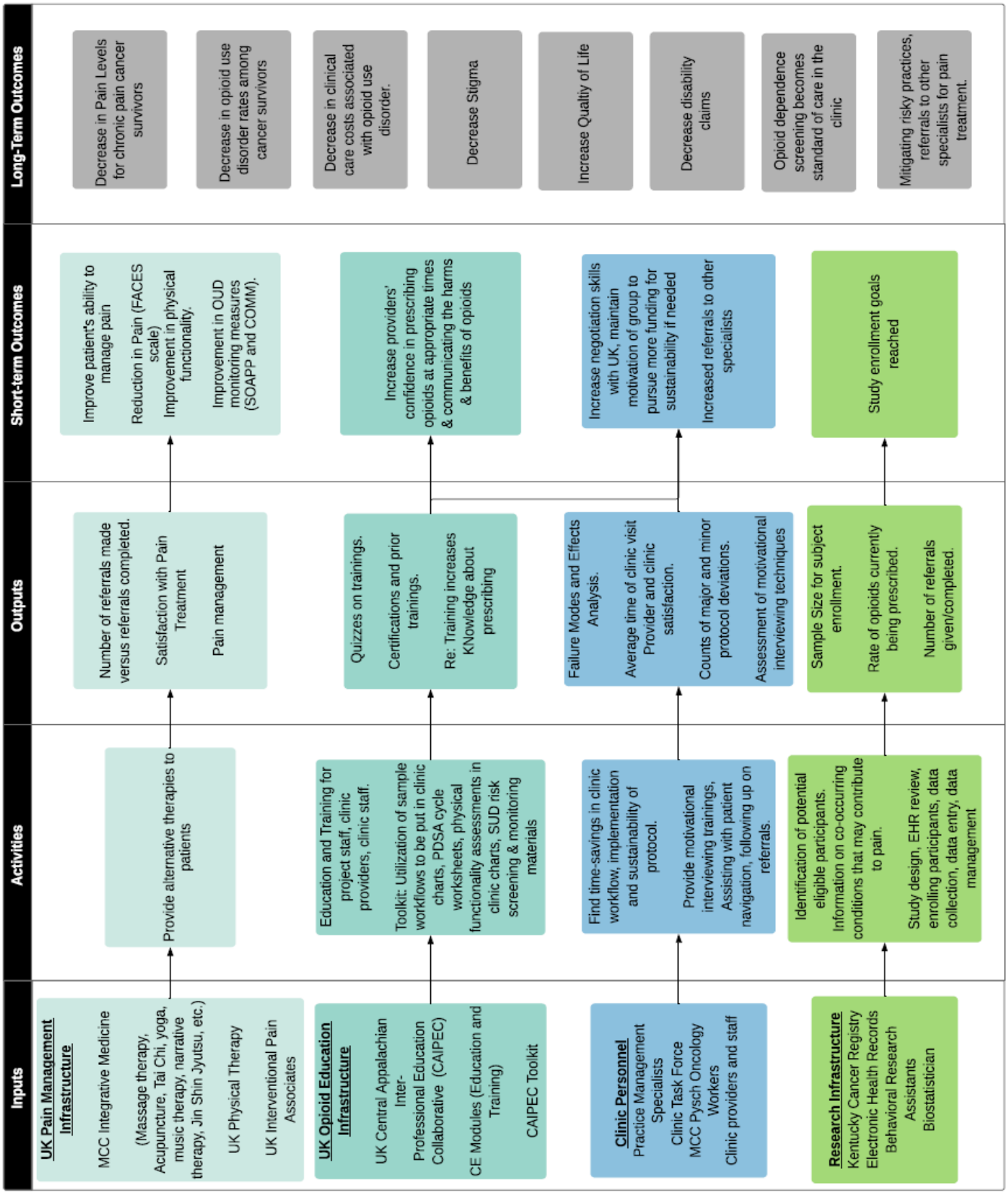
Current Opioid Misuse Measure (COMM)®

Please answer each question as honestly as possible. Keep in mind that we are only asking about the **past 30 days**. There are no right or wrong answers. If you are unsure about how to answer the question, please give the best answer you can.

Please answer the questions using the following scale:	**Never**	**Seldom**	**Sometimes**	**Often**	**Very Often**
	0	1	2	3	4
1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems?	O	O	O	O	O
2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (i.e., doing things that need to be done, such as going to class, work or appointments)	O	O	O	O	O
3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (i.e., another doctor, the Emergency Room, friends, street sources)	O	O	O	O	O
4. In the past 30 days, how often have you taken your medications differently from how they are prescribed?	O	O	O	O	O
5. In the past 30 days, how often have you seriously thought about hurting yourself?	O	O	O	O	O
6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?	O	O	O	O	O

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
7. In the past 30 days, how often have you been in an argument?	O	O	O	O	O
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	O	O	O	O	O
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	O	O	O	O	O
10. In the past 30 days, how often have you been worried about how you're handling your medications?	O	O	O	O	O
11. In the past 30 days, how often have others been worried about how you're handling your medications?	O	O	O	O	O
12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?	O	O	O	O	O
13. In the past 30 days, how often have you gotten angry with people?	O	O	O	O	O
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	O	O	O	O	O
15. In the past 30 days, how often have you borrowed pain medication from someone else?	O	O	O	O	O
16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?	O	O	O	O	O
17. In the past 30 days, how often have you had to visit the Emergency Room?	O	O	O	O	O

Appendix F. Logic Model



Appendix G. Gantt Chart	Year 1				Year 2				Year 3			
Activity	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Program Preparation, Training and Community Engagement	**Planning and Readiness Period**											
IRB Approval												
Hire Key Staff												
Order Supplies												
Develop and test database and surveys												
Educate and Train Key Staff and Clinic Providers												
Community Advisory Group Formation and Meetings												
Program Implementation												
Failure Modes and Effects Analysis												
Plan, Do, Study Act Worksheets												
Implementation in Clinic 1 (Q3, Month 7)												
Implementation in Clinic 2 (Q3, Month 9)												
Implementation in Clinic 3 (Q4, Month 11)												
Data Collection in All 3 Clinics - includes baseline measures												
Evaluation and Maintenance												
Key Informant Interviews												
Process Evaluation												
Fidelity Monitoring												
Outcome Evaluation												

Appendix H. Plan, Do, Study, Act Cycle Worksheet

PDSA (plan-do-study-act) worksheet

TOOL: Patient Feedback **STEP:** Dissemination of surveys **CYCLE:** 1st Try

PLAN

I plan to: We are going to test a process of giving out satisfaction surveys and getting them filled out and back to us.

I hope this produces: We hope to get at least 25 completed surveys per week during this campaign.

Steps to execute:

1. We will display the surveys at the checkout desk.
2. The checkout attendant will encourage the patient to fill out a survey and put it in the box next to the surveys.
3. We will try this for 1 week.

DO

What did you observe?

- We noticed that patients often had other things to attend to at this time, like making an appointment or paying for services and did not feel they could take on another task at this time.
- The checkout area can get busy and backed up at times.
- The checkout attendant often remembered to ask the patient if they would like to fill out a survey.

STUDY

What did you learn? Did you meet your measurement goal?

We only had 8 surveys returned at the end of the week. This process did not work well.

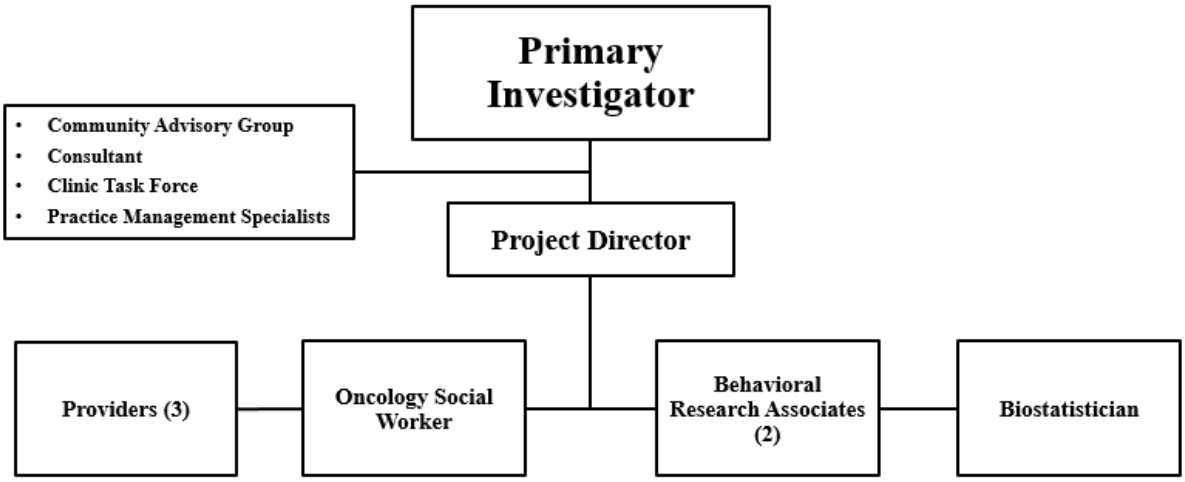
ACT

What did you conclude from this cycle?

Patients did not want to stay to fill out the survey once their visit was over. We need to give patients a way to fill out the survey when they have time.

We will encourage them to fill it out when they get home and offer a stamped envelope to mail the survey back to us.

Appendix I. Organizational Chart



BUDGET JUSTIFICATION

Primary Investigator: Hann Solo, DO, MHA, MPH; (10% / 5% / 5% FTE) Professor and Chief of Community Medicine, Director of the Kentucky Ambulatory Network (Practice Based Research Network). As the primary investigator of the CAIPEC grant funded by the Pfizer Consortium and a member of the Markey Cancer Center, Dr. Solo is well-suited to be the primary investigator of this grant. His role will include forming the Community Advisory Group; oversee the Clinic Task Force and Practice Management Specialist; provide consultation to clinics and act as final authority on workflow changes; review high-level progress reports of the project to ensure milestones are being met in accordance with the funding sponsor's guidelines; review potential participants' screening files and approve enrollment; assist in hiring and termination of key staff; act as the emergency contact for Adverse Events and Serious Adverse Events; disseminate findings to CAG, Partners, and Stakeholders.

Project Director: Jennifer M. Dolly Prothro, BA, MPH, CCRP; (100% FTE) Mrs. Dolly Prothro has served the Markey Cancer Center in research administration for the last five years, prior to which she served as the Project Manager for three years on the clinical research project "Separate and combined effects of the gabapentin and THC in humans discriminating THC" [R01 DA025605] and a clinical trial to investigate the initial safety, tolerability and efficacy of the GABA reuptake inhibitor tiagabine to reduce cannabis use in daily cannabis users (R01 DA036550; IND#101,109; clinicaltrials.gov ID NCT01511640. Her role will be to oversee all project staff other than the Clinic Task Force and Practice Management Specialist, monitor and

track progress, coordinate meetings, submit IRB documentation including protocol deviations and adverse events, and oversee dissemination of results.

Clinic Providers (3) (5% FTE each)

Clinic providers are expected to spend approximately 2 hours per week on the project. They will will be trained in motivational interviewing, opioid prescribing guidelines, appropriate pain management guidelines and therapies, and will be assessed per the Process Evaluation metrics. They will deliver the intervention to participants, provide referrals, and report interactions with each participant.

Oncology Social Worker (60% / 70% / 80%FTE)

Trains and assesses performance of providers and clinic champions in Motivational Interviewing. Assists in patient navigation. Mediator between providers, project staff, and participants.

Behavioral Research Associates (2) (40% FTE each)

Markey's Behavioral and Community-Based Research Shared Resource Facility hosts a team of dedicated Behavioral Research Associates who are exceptionally well-trained in quantitative behavioral research. Supports project implementation, screening, recruitment and tracking efforts, provides participant payments, review all data collection and ensure procedures have been followed according to Good Clinical Practice Guidelines, enter paper-based survey data, conduct minor data management as needed, create participant calendar schedules, etc.

Biostatistician/Data Manager (5% FTE)

Provides support for study design, study conduct, database building, and data management.

Practice Management Specialist (5% FTE)

Finds time savings in the clinic workflow to insert research protocol.

Clinic Task Force (2) (5% FTE each)

Maintains sustainability of protocol during project period, conducts Failure Modes and Effects Analysis.

Consultant

$1,000 to consult on best-practices and issues as they arise in the project period.

Equipment

$5,000 to purchase two iPads for data collection, a camera to record motivational interviewing training sessions, and three laptops for participant screening, data entry, data management, participant recruitment, etc.

Travel

$3,000 in Year 1. $10,000 in Years 2 and 3. Provides travel funds for professional development opportunities for project staff.

Research Incentives $6,000 for participant payments. Total of 1 screening appointment, and 3 clinic visits at $5 each. Estimated 300 participants to be screened per year.

Clinic Stipend

$20,000 to pay the clinic as an incentive to allow the study protocol to be implemented in their clinic.

CPH 746
Grant Application
Jennifer Dolly
BUDGET

September 1, 2020 - August 31, 2023

	Year 1					Year 2					Year 3				
Personnel	Effort	Salary		Fringe	Total	Effort	Salary		Fringe	Total	Effort	Salary		Fringe	Total
Principal Investigator	10.00%	$100,000	$10,000	$2,743	$12,743	5.00%	$103,000	$5,150	$1,413	$6,563	5.00%	$106,090	$5,305	$1,455	$6,760
Project Director	100.00%	$65,000	$65,000	$19,993	$84,993	100.00%	$66,950	$66,950	$20,592	$87,542	100.00%	$68,959	$68,959	$21,210	$90,169
Clinic Provider	5.00%	$180,000	$9,000	$2,222	$11,222	5.00%	$185,400	$9,270	$2,288	$11,558	5.00%	$190,962	$9,548	$2,357	$11,905
Clinic Provider	5.00%	$180,000	$9,000	$2,222	$11,222	5.00%	$185,400	$9,270	$2,288	$11,558	5.00%	$190,962	$9,548	$2,357	$11,905
Clinic Provider	5.00%	$180,000	$9,000	$2,222	$11,222	5.00%	$185,400	$9,270	$2,288	$11,558	5.00%	$190,962	$9,548	$2,357	$11,905
Behavioral Research Associate	40.00%	$30,000	$12,000	$5,022	$17,022	50.00%	$30,900	$15,450	$6,466	$21,916	50.00%	$31,827	$15,914	$6,660	$22,573
Behavioral Research Associate	40.00%	$30,000	$12,000	$5,022	$17,022	50.00%	$30,900	$15,450	$6,466	$21,916	50.00%	$31,827	$15,914	$6,660	$22,573
Oncology Social Worker	60.00%	$40,000	$24,000	$8,808	$32,808	70.00%	$41,200	$28,840	$10,584	$39,424	80.00%	$42,436	$33,949	$12,459	$46,408
Biostatistician / Data Manager	5.00%	$60,000	$3,000	$947	$3,947	10.00%	$61,800	$6,180	$1,950	$8,130	15.00%	$63,654	$9,548	$3,012	$12,561
Practice Management Specialist	5.00%	$50,000	$2,500	$840	$3,340	2.00%	$51,500	$1,030	$346	$1,376	2.00%	$53,045	$1,061	$357	$1,417
Clinic Task Force	5.00%	$50,000	$2,500	$840	$3,340	5.00%	$51,500	$2,575	$865	$3,440	5.00%	$53,045	$2,652	$891	$3,544
Clinic Task Force	5.00%	$50,000	$2,500	$840	$3,340	5.00%	$51,500	$2,575	$865	$3,440	5.00%	$53,045	$2,652	$891	$3,544
Consultant Costs					$1,000										
Equipment (1 camera, 2 iPads, 2 Laptops)					$5,000										
Travel					$3,000					$10,000					$10,000
Research Incentives ($20/person - 300 people)					$6,000					$12,000					$12,000
Clinic Stipend (time spent in workflow to conduct research)					$20,000					$20,000					$20,000
Printing					$1,000					$1,000					$1,000
Total Direct Costs					$248,219					$271,422					$288,263
F&A					$131,556					$143,854					$152,779
Total					$379,775					$415,276					$441,042
GRAND TOTAL		**$1,236,093**													