State of Michigan
Department of Licensing and Regulatory Affairs

Marijuana Regulatory Agency

VETERAN MARIJUANA RESEARCH (VMR) GRANT PROGRAM

2022

REQUEST FOR PROPOSALS

VETERAN MARIJUANA RESEARCH (VMR) GRANT

RESPONSE DOCUMENT

ESTIMATED TIMELINE	
Issue Date	April 1, 2022
Inquiries Due	April 15, 2022
Inquiries Response Posted	May 1, 2022
Proposals Due	June 1, 2022
Anticipated Start Date	July 30, 2022

PART V: INFORMATION REQUIRED FROM APPLICANT(S)

Applicant(s) must submit one proposal. Electronically submitted proposals must have a scanned signature or e-signature and cannot exceed 15 MB.

Applicant(s) must provide responses to each section below. Be as descriptive as possible and answer each question in its entirety; some questions have multiple components. In your responses, provide a straight-forward, concise description of the applicant(s)'s ability to meet the requirements of the RFP. Questions that do not apply should be answered "N/A."

V-A Identification of Organization

State the full name and address of the organization, the organization's federal identification number, the organization's telephone and fax numbers, and what percentage of the organization is located in Michigan.

BEGIN APPLICANT RESPONSE

Omni Medical Services Inc.
13 N Washington St
Ypsilatni, MI 48197-2617
P: 866-417-2002
F: 866-271-1135
EIN: 35-2656855

The 501(c)3 organization is located 100% in Michigan. The organizations' affiliated medical clinics in Michigan (30%), Ohio(30%), and Florida (40%) are managed by a separate LLC entity.

END APPLICANT RESPONSE

V-B Authorized Negotiator

State the name of one (1) contact person and his/her telephone number, fax number, and electronic mail address. The contact person must be authorized to be the negotiator for the proposed Grant Agreement with the State.

BEGIN APPLICANT RESPONSE

Dr. Ryan Lakin, MD JD
Sr. Project Manager and Primary Investigator
P: 866-417-2002
F: 866-271-1135
EIN: 35-2656855

END APPLICANT RESPONSE

V-C Method for Addressing the Problem The Michigan Regulation and Taxation of Marihuana Act.

State in succinct terms the applicant(s)'s proposed method for addressing the problem presented in

Section III-B, Problem Statement. Describe any significant obstacles the applicant(s) has had coordinating and managing clinical trial research.

BEGIN APPLICANT RESPONSE

This goal of this application is to obtain pilot funding for our Phase II clinical trial to study treatment of chronic pain and other conditions with medical cannabis. Omni Medical Services Inc is a 501c3 IRS recognized nonprofit clinical network that has 10 years of experience in successfully treating over 20,000 patients in multiple states with medical cannabis. Our phase 1 study was completed in January 2020 which showed a 58% reduction in opioid use in our cannabis patients. Our multi-aim study is registered on ClinicalTrials.gov with Identifier NCT03944447, and we have an FDA Research IND Number 156172 to study medical cannabis, in conjunction with one of the recently awarded DEA licensed federal medical cannabis growers, Biopharmaceutical Research Company (BRC), DEA license RB0600165, letter of support included in Attachemnts. Our project will not only involve studying the efficacy and safety of cannabis for chronic pain but will also provide patients directly with federally approved and sourced medical cannabis.

Medical cannabis has been legal in parts of the USA since 1996, with the stated intention of reducing pain (both acute and chronic) as well as for treatment of multiple other conditions. The original implementation of medical cannabis in the USA was implemented in California as a compassionate measure to treat the HIV/AIDS epidemic. Evolving research studies have shown promising outcomes for patients with chronic pain, multiple sclerosis, seizures, cancer, and several mental health conditions including PTSD and anxiety. Due to variable state law, social stigma, and restricted federal status, there has been an absence of multicenter, multistate, randomized and blinded clinical trials involving medical cannabis. The DEA has recently licensed private growers with schedule 1 licenses for cannabis research. Omni Medical Services has secured partnerships with two of these DEA licensed grow companies, Groff NA and Biopharmaceutical Research Company (BRC), who will provide federally approved and sourced cannabis to the Veterans involved in our study.

Using an online questionnaire, we conducted a Phase 1 observational clinical trial of 585 medical cannabis patients with CP treated by our clinical research centers between December 2018 and December 2019. Data collected included demographic information, changes in opioid use, quality of life, medication classes used, and medication side effects before and after initiation of cannabis usage. Among study participants, medical cannabis use was associated with a 57% decrease in opioid use, decreased number and side effects of medications, and an improved quality of life (59%). With our recent partnership with the DEA registered schedule 1 cannabis providers, Omni is launching its phase 2 clinical trial studying the efficacy and safety of cannabis to treat a wide range of chronic medical conditions. Our FDA-approved cannabis clinical trial (IND 156172, ClinicalTrials.gov Identifier: NCT03944447) has attracted multiple collaborators including academic institutions and medical device companies. This study of Michigan Veterans will flow seamlessly with our established clinical trial and network. In addition to recruiting Veterans within the state of Michigan, we will conduct our study protocols with our intended academic collaborators who have an extensive history of conducting clinical trials, exercising financial and management oversight, and reporting results. Furthermore, these institutions will be instrumental in dispensing DEA schedule 1 cannabis to Veterans due to their existing infrastructure to handle controlled substances for research. Omni's multiple cannabis treatment clinics will have the ability to work with these entities and perform FDA-approved IND clinical trials with federally approved and sourced medical cannabis. Little information is available to guide clinicians, and further research is needed to address the major gaps in the knowledge required for optimal treatment outcomes and mitigate the disastrous failure that is the opioid epidemic. This clinical trial will study medical cannabis human subjects to safely establish guidelines for use in chronic pain patients.

The public health concern that has emerged involves the increasing suicide rate and other long-term impact on quality of life that US veterans with Post Traumatic Stress Disorder (PTSD), anxiety, and chronic pain must face. Unfortunately, more than 6,400 military veterans committed

suicide in 2018. Clinical research documents that a significant portion of veterans seeking assistance for their conditions report utilizing cannabis to control symptoms, especially in states where medical cannabis laws allow relatively easy and safe access. Furthermore, the VA has taken a relaxed stance and publicly acknowledged that benefits such as health coverage and service connection disability payments will not be suspended for cannabis use by Veterans.

According to the U.S. Department of Veterans Affairs' 2020 National Veteran Suicide Prevention Annual Report, 6,435 U.S. veterans died from suicide in 2018. As there were 20.1 million U.S. Veterans in 2018, this equals a rate of 27.5 per 100,000 veterans per year. For Veterans Health Administration (VHA) patients diagnosed with depression, the suicide rate in 2018 was 66.4 per 100,000 in 2018. For VHA patients diagnosed with anxiety, the suicide rate was 67.0 per 100,000. VHA patients with any mental health or substance use disorder diagnosis had a suicide rate of 57.2 per 100,000. The first FDA-regulated, placebo-controlled, double-blind study on the use of marijuana among veterans with diagnosed PTSD was published in March 2021.[1,2] A study published in December 2020 assessed PTSD symptoms and functioning every three months over the course of a year in two samples of participants diagnosed with PTSD: those using marijuana, and those not using marijuana.[3] These studies have shown promising results. However, more clinical trials are needed to determine the efficacy of marijuana in treating the medical conditions of U.S. armed services veterans and preventing veteran suicide. A provision of the Michigan Regulation and Taxation of Marihuana Act. provides funding for research on the effectiveness of marijuana (hereafter, cannabis) to treat "*the medical conditions of United States Armed Services Veterans and preventing Veteran suicide*". There is established evidence that various chronic conditions, both physical and mental, can lead to increased risk of suicide.[4,5]

Male Veterans with anxiety disorders have double the risk of dying by suicide as those without; with a 3.5-fold increase for women risk.[6] Chronic pain conditions are associated with the risk of suicide and overdose stemming from the use of opioids.[7] Lastly, insomnia is associated with 1.5

times higher odds of suicide attempt among Veterans, even after adjustment for factors associated with suicide risk, including substance use disorder, anxiety, bipolar disorder, and depression.[8] This application proposes an assembly of multicenter randomized clinical trials (RCTs) that test the effectiveness of various cannabis constituents in treating common medical conditions, specifically chronic pain, anxiety, and PTSD, that increase the risk of suicide in Veterans.

This study will utilize an anonymous novel online questionnaire (using REDCap software) to determine study participants' qualifying condition(s) for medical cannabis use, cannabis ingestion method, frequency of use, prescription drug use, and demographic information. Secondary factors will include evaluation of pain control, quality of life metrics, any adverse side effects from cannabis use, as well as changes in adjunctive treatments. Participants may be given medical cannabis recommendations and certifications by Omni physicians commensurate with the state law in which the encounter occurs. Grant funds will be allocated to purchase cannabis from a Michigan licensed producer. After we obtain our DEA Schedule I license to distribute cannabis for human research (pending application at the time of this grant submission), we will provide our patients directly with this federally approved and sourced medical cannabis.

Surveys will be administered to legal medical cannabis patients of Omni medical facilities conducting clinical research in Michigan, with expansion to other states as permitted by the VMR and as we recruit involvement with other potential collaborators. In order to collect patients' responses through the REDCap system, we will need to collect names, dates of birth, residential addresses, and email addresses from patients. This information is collected within the scope of standard medical practices and is indeed required by the various states' medical cannabis laws to participate in the programs. However, this information will be decoupled from responses as detailed below. We will use anonymous REDCap survey links, which will be sent to each study participant. Patients will be linked to their state-issued cannabis registry ID number, which is

assigned at the time of registration. In states without a state program that issues unique IDs, patients will be assigned their own study IDs based on the guidelines below: the first two letters of their mother's maiden name, the first two letters of their father's first name, and the day (e.g. 06 for the 6th) of their mother's birthday. The REDCap software can be programmed to automatically send out emails at 3-month intervals; however, the clinical research staff will be tasked with contacting patients with unanswered questionnaires. This method will allow clinical research staff to track patient responses and attempt contact for survey questionnaire completion.

This study will measure the aspects of actual cannabis consumption using the Octopi smartphone app in which participants will enter data on these use parameters each time they use cannabis. Octopi can also be used on any internet-enabled device if an individual does not have a smartphone. Our research study will involve incorporation of RYAH-Medtech company's devices into our protocols. RYAH has developed an inhaler and a transdermal patch for both hemp-derived CBD and cannabis. RYAH has programmed an integrated phone app for tracking product use and patient response. They are currently involved in clinical trials in Europe. Omni Medical will integrate the partnership with RYAH for several reasons. Primary goals will involve using their integrated smart phone app to collect and secure large quantities of data. Secondary goals will include FDA approval as a medical device for consuming CBD and/or medical cannabis. The specific cannabis strain will be tracked using scannable QR codes programed into the smart phone app. This will allow us to track patient feedback and capture data on usage. Use of the devices would be completely voluntary by study participants. This can be achieved with concomitant integration of the RYAH inhalation device and app, and the Octopi smartphone/internet app. In addition, we will objectively measure sleep and activity data using wearable sensors (e.g., Fitbits, Apple Watches), allowing a detailed and reliable method of observing how cannabis affects health.

As part of the study, participants will submit a sample for genotyping using Endocanna's EndoDNA genomic testing platform (EndoDNA.com) ; results will inform the research team whether specific genetic profiles may correlate with treatment response. The test analyzes more than 675,000 Single Nucleotide Polymorphisms (SNPs) related to the endocannabinoid system. These specific SNPs exhibit genetic variations which have been shown in previous research to be associated with specific medical conditions, mental wellness, and physical health. Endocanna Health's team of world-renowned scientists, geneticists, cannabis experts, physicians, and researchers have been perfecting the science behind endocompatibility for years. The result is the most comprehensive endocannabinoid DNA test available today, with the potential for strain-specific predictive outcomes with cannabis treatment based on genotyping. We will partner with an innovative device company, BioSensics provides technical and global operation services to support and facilitate the use of wearable sensors and digital technologies in clinical studies and trials. A biometric wearable device called the Biosensic digital biomarker will be provided to each participant. High Resolution Photoplethysmography (PPG) Signal Capture will be used to capture data like HRV, SpO2, Respiratory Rate, etc., through Remote Monitoring. This data will be clustered and analyzed by Machine Learning Neural Network for Building Predictive Inferences.

An additional study arm will use the innovative Oblend device. Altopa, a C-corporation headquartered in Seattle, WA with offices in Research Triangle Park, NC, was formed in 2016 to address the largest challenge with botanical medicine: lack of consistency. Realizing that plant-medicine will never be considered mainstream medicine unless it was consistent, Altopa has solved the medical cannabis industry's main challenges by developing the Oblend, the 1st botanical compounding platform. The Oblend is a patented device that creates personalized, consistent formulations with pharma-grade precision. The Oblend, about the size of a Keurig coffee maker, is similar to an ink jet printer. It holds proprietary, chip encoded canisters filled with high quality extracts and isolates. Using Altopa's patented microfluidics-based technology to perform time/pressure dosing of isolated ingredients in microliter increments, the Oblend

dispenses each botanical ingredient in micro-metered amounts to create very precise, consistent formulations. Altopa's team of engineers, scientists and experts have tested hundreds of plant extracts including broad spectrum oils, isolates, and distillates to find the highest quality, purity, and most effective ingredients. We hold our sources and ourselves to standards that exceed current regulatory requirements. We've developed proprietary processes, ingredient preparations, and strive to continually evolve our knowledge and capabilities to reduce variability, to increase product consistency and predictability, and to target specific benefits.

Every ingredient must pass Altopa's quality control processes before approval for use in the Oblend. These quality control processes include Certificates of Analysis and Altopa's proprietary gravimetric dissection process which characterizes each ingredient for use in the Oblend. Once the ingredient has passed through Altopa's quality control processes, the properties of the ingredient are entered in the cloud and linked to the cannister's smart chip. Then, the cannister is filled with the ingredient. If an ingredient is introduced from a new batch, then the process repeats.

Similar to an ink jet printer, the Oblend contains canisters filled with botanical ingredients such as isolated CBD, CBN, CBG, as well as terpenes such as linalool, beta Caryophyllene, limonene, humulene, alpha pinene, and myrcene. Oblend's platform is unlimited and can contain hundreds of ingredient-filled cannisters if the market demands. The minimum dispense varies based on the characteristics of the ingredients, but typically, the Oblend is capable of dispensing amounts less than one microliter.

When the Oblend creates a product, the platform tracks the information, and a label is printed for each product which includes the details of the formulation's ingredients and a QR code which enables seed to sale traceability. Each cannister communicates with the platform regarding the usage information and amount remaining, and when it is necessary to add additional ingredients to the cannister.

Altopa has designed the Oblend platform for care providers who would like to recommend botanical formulations for their patients. Prior to the Oblend and unlike other healthcare sections, care providers are unable to control their patient's medication, and patient feedback on the efficacy is lacking. With the Oblend platform, care providers can recommend a botanical formulation with pharma-grade. The Oblend dispenses each active botanical ingredient directly into containers to create tinctures and eventually vapor cartridges and topicals within minutes.

Then, based on the patient's feedback, the care provider can adjust the formulation until each patient finds the perfect, personalized botanical formulation that addresses the individual's unique needs. The Oblend platform collects data including patient demographics, efficacious clusters of ingredients for medical ailments, optimal delivery modalities, and dosing protocols to enhance user experience, improve patient outcomes & support clinical research. After the care provider recommends an Oblend formulations and the payment is remitted, Oblends fulfill these orders by dispensing lab-validated, precise formulations which can be delivered to the care provider or directly to the patient.

In addition to providing Oblend products to Veterans in the PTSD and anxiety study aims, we will perform the first known clinical trial using an opioid weaning protocol with cannabis and/or CBD for Veterans managing chronic pain wishing to decrease their opioid use. Numerous pre-clinical studies have shown that cannabis and cannabinoids decrease opioid withdrawal symptoms. This study aim will be achieved with the Oblend using sequential liquid preparations gradually tapering down opioids and increasing THC delta-9. This liquid form is available from an established licensed Michigan cannabis supplier, Total Health Concepts. Omni has a terminal distributor license for schedule II opioid distribution, and our lead pharmacist has extensive experience with liquid opioid preparations. The expected enrollment will be 10 patients in this arm over the first year, with reassessment for additional enrollment after the first year.

An appropriate control comparator group will be used. Our supplier of DEA licensed/sourced cannabis will incorporate established manufacturing processes to extract the cannabinoids while maintaining product characteristics to blind study subjects. We believe in the importance and scientific necessity in conducting randomized, double-blind, placebo-controlled trials for the proposed indications and that such trial designs are necessary in order to provide interpretable data and determine whether the study drug will help or harm patients with chronic pain. To facilitate interpretation and ensure the integrity of the study results, we will incorporate a placebo control and procedures for subjects and investigators to remain blinded to treatment assignment. To facilitate manufacture, the bulk plant material needs to be processed to acceptable particle size and consistency. Placebo material can be prepared by repeated solvent (typically ethanol) extraction and used in bulk or in cigarette manufacture. Alternatively, cigarettes can be manufactured from processed cannabis in smaller scale using table-top cigarette maker machines. Several million cigarettes in various phytocannabinoid concentrations and placebos have been manufactured in this way and have been available for use through NIDA as medicinal dosage formulations or for research. As such, our affiliated DEA licensed/sourced manufacturer can replicate such placebo protocols.

Veterans must be currently using cannabis products for pain, anxiety, or insomnia symptom management at the time of enrollment. To reduce expenses, travel burden, and exposure to COVID-19, all study visits will be conducted via video conference or phone call. Participants will be recruited through: 1) Omni Medical Services' existing multistate clinical network; 2) our proposed potential academic collaborators, and; 3) partnering with advocacy groups Veterans for Cannabis (vfcusa.com). The overall strategy is to recruit veterans who use cannabis to manage medical conditions such as chronic pain, anxiety, and PTSD, with specific goals of preventing suicide. Data will be published in high-impact medical journals and the findings will be sent to the FDA for approval of continuing on to phase III & IV trials.

Aim 1: Chronic Pain

The primary objective is to assess the efficacy and safety of medical cannabis as medicine for treatment of chronic pain and other chronic debilitating diseases. Our goal is to recruit 100 veterans for this subgroup. Pain will be measured by Brief Pain Inventory (BPI) numeric scale. Change from baseline in BPI will be assessed at 3-month intervals. For prospective associations between cannabis use and outcomes, use of a lagged mixed-effects models will examine temporal associations between cannabis use and pain severity, opioid sparing, and patient satisfaction. Data will be analyzed from baseline and the annual follow-up waves. We will use the Positive and Negative Suicide Ideation (PANSI) scale to assess suicidality in all study participants over the course of the study. Veterans will be randomized into one of four different THC (Δ9-tetrahydrocannabinol) :CBD (cannabidiol) dose conditions (High THC:High CBD; HighTHC:Low CBD; Low THC:High CBD, and Low THC:Low CBD).

Aim 2: Anxiety

Our goal is to recruit 100 veterans for this subgroup. Veterans will be assessed using the Beck Anxiety Inventory (BAI). The BAI is a rating scale used to evaluate the severity of anxiety symptoms. The BAI contains 21 self-report items (Beck et al., 1996b). The items reflect symptoms of anxiety, including: numbness or tingling, feeling hot, wobbliness in legs, ability to relax, fear of the worst happening, dizziness or lightheadedness, pounding or racing heart, unsteadiness, feeling terrified, feeling nervous, feeling of choking, hands trembling, feeling shaky, fear of losing control, difficulty breathing, fear of dying, feeling scared, indigestion or abdominal discomfort, faintness, face flushing, and sweating. Each item allows the patient four choices from no symptom to severe symptom. For each item, the patient is asked to report how he or she has felt during the past week. The items are scored as 0, 1, 2, or 3. The score range is 0–63. A total score

of 0–7 is considered minimal range, 8–15 is mild, 16–25 is moderate, and 26–63 is severe. The BAI can be given to the same patient in subsequent sessions to track the progression or improvement of the anxiety. The test is designed for self-report in individuals aged 17 and up. The BAI has been found to discriminate well between anxious and nonanxious diagnostic groups and, as a result, is useful as a screening measure for anxiety. The reliability coefficient is 0.92. The test–retest reliability is 0.75. Correlations of the BAI with a set of self-report and clinician-rated scales were all significant (e.g., Spearman rank correlation coefficient (r_s) > 0.50). We will use the Positive and Negative Suicide Ideation (PANSI) scale to assess suicidality in all study participants over the course of the study.[8]

Study Arm 3: PTSD

This randomized double-blind clinical trial will examine effects of THC and CBD on self-reported PTSD symptom severity and suicidal ideation. A total of 100 veterans will be enrolled into this subgroup. Treatment will be conducted with scheduled reassessments after the initial 12 weeks, and again at 6-, 9-, and 12-month intervals.. Study duration for each participant will be approximately 1 year from the time he/she is enrolled in the study. The primary outcomes of the proposed study include change from baseline (pre-treatment) to the end of the 12-week treatment phase (post-treatment) in PTSD symptom severity and suicidal ideation. PTSD will be assessed with the Post- Traumatic Stress Disorder Symptom Checklist for DSM-5 (PCL-5)[9] and Clinician-Administered PTSD Scale for DSM-5 Total Severity Score (CAPS-5).[10] The CAPS-5 is a clinician interview that determines the presence and severity of PTSD symptoms and allows for assessing changes in symptom severity over time.[11] Suicidality will be assessed using the Columbia Suicide Severity Rating Scale (C-SSRS) and Suicide Behavior Questionnaire- Revised (SBQ-R) . The C-SSRS is a clinician-administered assessment, and the SBQ-R is a self-administered questionnaire that will be measured at the specified follow-up visits.[12]

Secondary Outcomes- All arms

Secondary objectives include evaluating increases or decreases in quality of life, and increases or decreases in concomitant opioid use. Our study methods incorporate sophisticated data/software platforms including Octopi, RYAH, and Biosensics, which will examine preferences for routes of administration, preferences for THC / CBD ratios, and biopharmacokinetic responses. Categorical factors will be summarized using frequencies and percentages, while continuous measure distributions will be described using means, standard deviations, and quartiles of interest.

END APPLICANT RESPONSE

V-D Management Summary

(1) Describe management procedures that will be used by the organization to complete the proposed project.

(2) Describe the organization's quality control measures, including measures for ensuring compliance as well as eligibility determination. In your description, include information regarding separation of duties.

(3) Selected applicant(s) must provide fiscal control and financial accounting procedures that will assure that grant funds will be accounted for and properly dispersed in a way that will allow the Issuing Office to clearly review and verify all grant related expenditures. Describe the organization's internal control policy:

- Identify the type of accounting system/software the organization will use to account for grant funds,
- Identify how duties will be separated,
- Describe how the organization will account for grant funds, i.e., will grant funds be placed in a separate bank account, will the grant funds be assigned a unique code(s) within the organization's overall accounting system. Ensure funds are maintained in a non-interest- bearingaccount.
- Indicate whether internal and external audits of the organization's operations are performed on an annual basis. Selected applicant(s) must provide a copy of the organization's most recent audited financial statement as well as a copy of the organization's most recent single audit as required by OMB Circular 200.36

(4) Describe your agency's data security plan.

BEGIN APPLICANT RESPONSE

(1-3) Management Procedures, Quality Control Measures, and Financial Accounting Procedures

The research team, including PI's, Co-PIs, and Co-sponsor research departments will meet on a

monthly basis, or as needed, via video teleconference. An independent audit or review will be performed each quarter, which goes above and beyond standard compliance with regulatory requirements. Please see the Appendix for the letter from our full-service CPA firm of Metzler Locricchio Serra and Company. MLS+Co (www.mlscopa.com) is based in Troy, Michigan and has consistently ranked in the top ten of Michigan accounting firms. The Company has been in business for 40 years and handled all of the business for Omni for 28 years. Mr Michael Locricchio, one of the principals/partner is a CPA and lawyer and will personally oversee the account along with the grant administrator. The Company will oversee and have fiscal responsibility over a non interest bearing dedicated bank account currently established at PNC bank in Farmington Hills. All checks will be co-signed by the grant administrator and MLS+Co and disbursed in a prescribed manner using generally accepted accounting principals. The Company will provide a recent audited financial statement prior to funding and audited quarterly reports on all grant expenditures.

(4) The study will utilize an Independent Safety Monitor (ISM) Physician and Health Law Attorney with relevant expertise whose primary responsibility is to provide independent safety monitoring in a timely fashion. This is accomplished by review of adverse events, immediately after they occur or are reported, with follow-up through resolution. The ISM evaluates individual and cumulative participant data when making recommendations regarding the safe continuation of the study. Hardcopies of the study visit worksheets will be provided for use as source document worksheets for recording data for each participant enrolled in the study. Data recorded in the electronic case report form (eCRF) derived from source documents should be consistent with the data recorded on the source documents. Clinical data (including adverse events (AEs), concomitant medications, and expected adverse reactions data) and clinical laboratory data will be entered into Office Ally Electronic Health Records System, a 21 CFR Part 11-compliant data capture system. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source

documents. Study documents should be retained for a minimum of 2 years or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study intervention. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without prior approval of the Primary Investigator. REDCap is a secure web application for building and managing online surveys and databases. While REDCap can be used to collect virtually any type of data in any environment (including compliance with 21 CFR Part 11, FISMA, HIPAA, and GDPR), it is specifically geared to support online and offline data capture for research studies and operations. The REDCap Consortium, a vast support network of collaborators, is composed of thousands of active institutional partners in over one hundred countries who utilize and support their own individual REDCap systems.

IRB Review/Ethics/Informed Consent

This study has undergone rigorous scrutiny and approval by an IRB. Consent forms describing in detail the study goal, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention. Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be IRB-approved, and the participant will be asked to read and review the document. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. Participants must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, before the participant undergoes any study-specific procedures. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

Risk/Safety Information

Cannabis is generally tolerated well by patients. Any side effects tend to be mild and temporary, usually lasting one week or less as patients adjust. Common side effects include irritated throat, dry mouth, elevated heart rate, mild time and space disorientation, mild euphoria, a general sense of well-being, and in some instances drowsiness and decreased motivation. Preclinical data exists to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Previous experience with the drug in humans includes studies from foreign research protocols. Meta-analyses have shown an extremely low occurrence of adverse reactions or negative side effects with medical cannabis use in humans. All of the trials included in this review were conducted since 2003. This review has identified 18 trials that taken together have demonstrated a modest analgesic effect in patients, 15 of these were in neuropathic pain with five in other types of pain, one in fibromyalgia, one in rheumatoid arthritis, one as an adjunct to opioids. Several trials reported significant improvements in sleep. There were no serious adverse events. Drug related adverse effects were generally described as well tolerated, transient or mild to moderate and most commonly consisted of sedation, dizziness, dry mouth, nausea and disturbances in concentration.5 A recent systematic review reported on the so-called cannabinoid hyperemesis syndrome.6 This is currently the only known cannabis-related adverse reaction noted on the ICD-10 manual, and our questionnaire will specifically address the prevalence and incidence of the syndrome. Additionally, observational studies of patients using medical cannabis have been performed in the United States. The University of Michigan published findings showing opioid-sparing outcomes in medical cannabis patients. The University of Michigan surveyed patients from Omni Medical Service's clinics, and our clinical network was the first private medical network to partner with a major United States university to research medical cannabis use.

Any negative side effects must be reported to the Physician with the 90-day questionnaire, or as needed during the interim. Most states, including our three primary clinical study states of Ohio, Florida, and Michigan, have a dedicated 24-hour emergency hotline to report any medical cannabis emergencies or negative side effects. This study claims categorical exclusion for environmental analysis requirements under 25.30, 25.31, and 25.40 in CFR Title 21. A study site investigator will order baseline liver function

panels and urinalysis that can be completed at study locations or outpatient laboratory facilities. These laboratory studies will be completed on an annual basis, or at the discretion of the study investigator.

This study shall address adverse events consistent with FDA guidelines. Adverse events will be defined as any adverse event caused by a drug. An adverse event (also referred to as an adverse experience) can be any unfavorable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, and does not imply any judgment about causality. An adverse event can arise with any use of the drug (e.g., off-label use, use in combination with another drug) and with any route of administration, formulation, or dose, including an overdose. Suspected adverse reactions are the subset of all adverse events for which there is a reasonable possibility that the drug caused the event. Inherent in this definition, and in the requirement to report suspected adverse reactions, is the need for the sponsor to evaluate the available evidence and make a judgment about the likelihood that the drug actually caused the adverse event. We consider the application of the reasonable possibility causality standard to be consistent with the discussion about causality in the International Conference on Harmonization (ICH) E2A Guideline ("ICH E2A guidance"). Adverse reactions are a subset of all suspected adverse reactions where there is reason to conclude that the drug caused the event. An adverse event or suspected adverse reaction is considered "unexpected" if it is not listed in the investigator brochure or is not listed at the specificity or severity that has been observed; or, if an investigator brochure is not required or available, is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended. An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. An adverse event or suspected adverse reaction is considered "life-threatening" if, in the view of either the investigator or sponsor, its

occurrence places the patient or subject at immediate risk of death. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death. This study shall use the WHO-UMC causality assessment system to determine adverse event causality.

END APPLICANT RESPONSE

a. Work Plan

Provide clear and concise work plans for meeting the following components, with detailed explanation:

1) Provide for the coordination and overseeing of clinical trial(s) to determine the efficacy of marijuana in treating the medical conditions of U.S. armed services veterans and preventing veteran suicide.
2) Recruit and evaluate researchers to accomplish the goals of this grant.
3) Demonstrate the ability to work with researchers who can garner the United States Food and Drug Administration approval for the clinical trials.
4) Ensure the maximum amount of grant dollars are used to coordinate and oversee clinical trials with a minimal amount of grant dollars used for administrative costs.
5) Work with organizations closely tied to veterans and veterans' programs.
6) Provide the Grant Administrator with a grant budget to which monitoring and reporting will be tied. Please see attachment A for the budget template to be used.
7) Establish research goals, approve projects, exercise financial and management oversight, and document and review results.
8) Publish the results of the clinical trials.

BEGIN APPLICANT RESPONSE

1. **Provide for the coordination and overseeing of clinical trial(s) to determine the efficacy of marijuana in treating the medical conditions of U.S. armed services veterans and preventing veteran suicide.**

This study will be led by the PI and Co-Investigator, of whom have extensive experience in clinical trials, with specific focus and interest in chronic pain, anxiety, PTSD, and cannabis/CBD. The PI, Dr. Lakin, has served as medical director of Omni Medical Services. Dr. Lakin completed a clinical research fellowship at Cleveland Clinic/ Case Western in Ohio, and has multiple national conference presentations and publications.

2. **Recruit and evaluate researchers to accomplish the goals of this grant.**

Omni Medical Services has a dedicated network of clinicians, pharmacists, and administrators who will successfully administer the goals of this clinical trial. Dr. Lakin has been involved in prior NIH-funded human clinical trials. He has extensive experience in clinical trial design, implementation, and inevitable publication of trial results, as well as considerable expertise in the clinical aspect of medical cannabis and treating patients with medical cannabis. Unlike other

academic applicants for this grant whose university affiliations prohibit performing recommendations for cannabis for their patients, Dr. Lakin has been actively treating cannabis in the Omni Medical network for nine years in multiple states. In addition to recruiting Veterans within the state of Michigan, we will conduct our study protocols with our intended academic collaborators with an extensive history of conducting clinical trials, exercising financial and management oversight, and reporting results. Since the majority of clinical encounters will take place over telemedicine, any Co-Investigators can interact with the clinical trial participants regardless of varying physical location. Furthermore, these institutions will be instrumental in dispensing DEA schedule 1 cannabis to Veterans due to their existing infrastructure to handle controlled substances for research. Omni's multiple cannabis treatment clinics will have the ability to work with these entities and perform FDA-approved IND clinical trials with federally approved and sourced medical cannabis.

3. **Demonstrate the ability to work with researchers who can garner the United States Food and Drug Administration approval for the clinical trials.**

Dr. Lakin has overseen Omni's phase I clinical trial assessing cannabis and chronic pain. He has coordinated with the FDA on behalf of Omni to receive the Investigation New Drug application (IND 156172) for cannabis and an approved clinical trial using cannabis. Omni has an extensive multistate clinical network and experience with treating more than 20,000 patients with medical cannabis. Omni has entered into partnerships with the newly licensed DEA schedule I cannabis for research entities and we will be dedicating grant funds to have this federally approved cannabis available for the study participants.

4. **Ensure the maximum amount of grant dollars are used to coordinate and oversee clinical trials with a minimal amount of grant dollars used for administrative costs.**

Omni Medical Services is a self-sufficient 501c3 non-profit entity will very minimal

administrative costs. Unlike the large university applicants, we will not require a significant percentage of our budget to support academic infrastructures. The majority of our budget will be dedicated to providing veterans will medical cannabis, study supplies such as inhalers and biometric devices, partnerships with Veteran advocacy groups, and the remainder towards covering salary for project leads.

5. **Work with organizations closely tied to veterans and veterans' programs.**

   Omni Medical Services has partnered with partnering with advocacy groups Veterans for Cannabis (vfcusa.com). This organization has been advocating for cannabis access for Veterans for many years. VCF will coordinate participant recruitment, advertising, virtual visits, and assist with medication procurement.

6. **Provide the Grant Administrator with a grant budget to which monitoring and reporting will be tied. Please see attachment A for the budget template to be used.**

   Please see the attached budget provided by the grant administrator for our study proposal.

7. **Establish research goals, approve projects, exercise financial and management oversight, and document and review results.**

   Omni Medical Services has established itself in Michigan and other states as a premier provider of cannabis treatment and patient advocacy. Our continuing research goals are aligned with the goals of this grant.

8. **Publish the results of the clinical trials.**

At the conclusion of this clinical trial, we will submit our data to the FDA as part of the required ongoing review process with our IND and clinical trial. Omni will use this data, along with our ongoing phase II clinical trial data, to submit for phase III approval. Research data and outcomes will be submitted to national conferences and scientific journals for publication.

END APPLICANT RESPONSE

b. Current and Prior Experience and Funding Disclosure

Current and prior experience in administering clinical trials is important to the selection process. Each applicant(s) must provide a copy of the organization's most recent audited financial statement and single audit (if applicable). The audited financial statement and single audit must be sent under separate cover.

Proposals submitted by applicant(s) should include:

i. A description of the organization's experience in conducting the type of work proposed. Include current activities and activities for the previous ten years. Include project results.

ii. If applicant(s) received a similar grant award from the State of Michigan in prior years for the type of project proposed, provide a summary of project accomplishments. Include a plan for addressing and resolving past problems.

iii. Current funding source(s) and the level of funding for the current year and the previous ten years.

BEGIN APPLICANT RESPONSE

(1) A description of the organization's experience in conducting the type of work proposed. Include current activities and activities for the previous ten years. Include project results.

Dr. Lakin has overseen Omni's phase I clinical trial assessing cannabis and chronic pain. He has coordinated with the FDA on behalf of Omni to receive the Investigation New Drug application (IND 156172) for cannabis and an approved clinical trial using cannabis. We have made connections with three academic institutions which have expressed interest in acting as co-investigator sites for our project. Due to time constraints and the lengthy approval process for academic institutions to contract with outside entities, we did not get permission to name them in the grant language. We represent and warrant that if we get funding, we will establish contracts

and get approval through the VRM program to allocate grant resources. The institutions that have expressed interest in working with our project all have extensive experience in grant adminsitration, working with the NIH and FDA, and publishing high impact research

(2) If applicant(s) received a similar grant award from the State of Michigan in prior years for the type of project proposed, provide a summary of project accomplishments. Include a plan for addressing and resolving past problems.

Prior

N/A

(3) Current funding source(s) and the level of funding for the current year and the previous ten years.

Current/Prior

Lakin, RO

NIH/National Heart Lung Blood Institute

K23HLOBO247

Endothelial Function in Human Arteries

The goal of the clinical trial was to assess the effects of regional L-arginine supplementation in patients with chronic lower extremity occlusive disease undergoing angiography. This project led to multiple national conference presentations and publications in high-impact scientific journals.

BioSensics

BioSensics has received over $40 million dollars of funding from the NIH over the past 10 years. They will be an integral part of understanding cannabis as treatment, validating biomarkers, and finalizing assessments of study endpoints. Please see the full list of NIH grant support at https://reporter.nih.gov and search “Biosensics”.

END APPLICANT RESPONSE

II-B Personnel

Selected applicant(s) must be able to staff a project team that clearly possesses skill and experience in

coordinating clinical trials. In the narrative, identify the authorized contact person and key personnel to be involved with this project by name and title and provide a brief summary of their experience, qualifications, and the work to be performed.

If other organizations will be playing a role in the proposed project, provide sufficient background information that will give the Issuing Office a reasonable understanding of each organization's qualifications.

Include a detailed organizational chart including names, titles, and geographic location of all individuals that will contribute to the project.

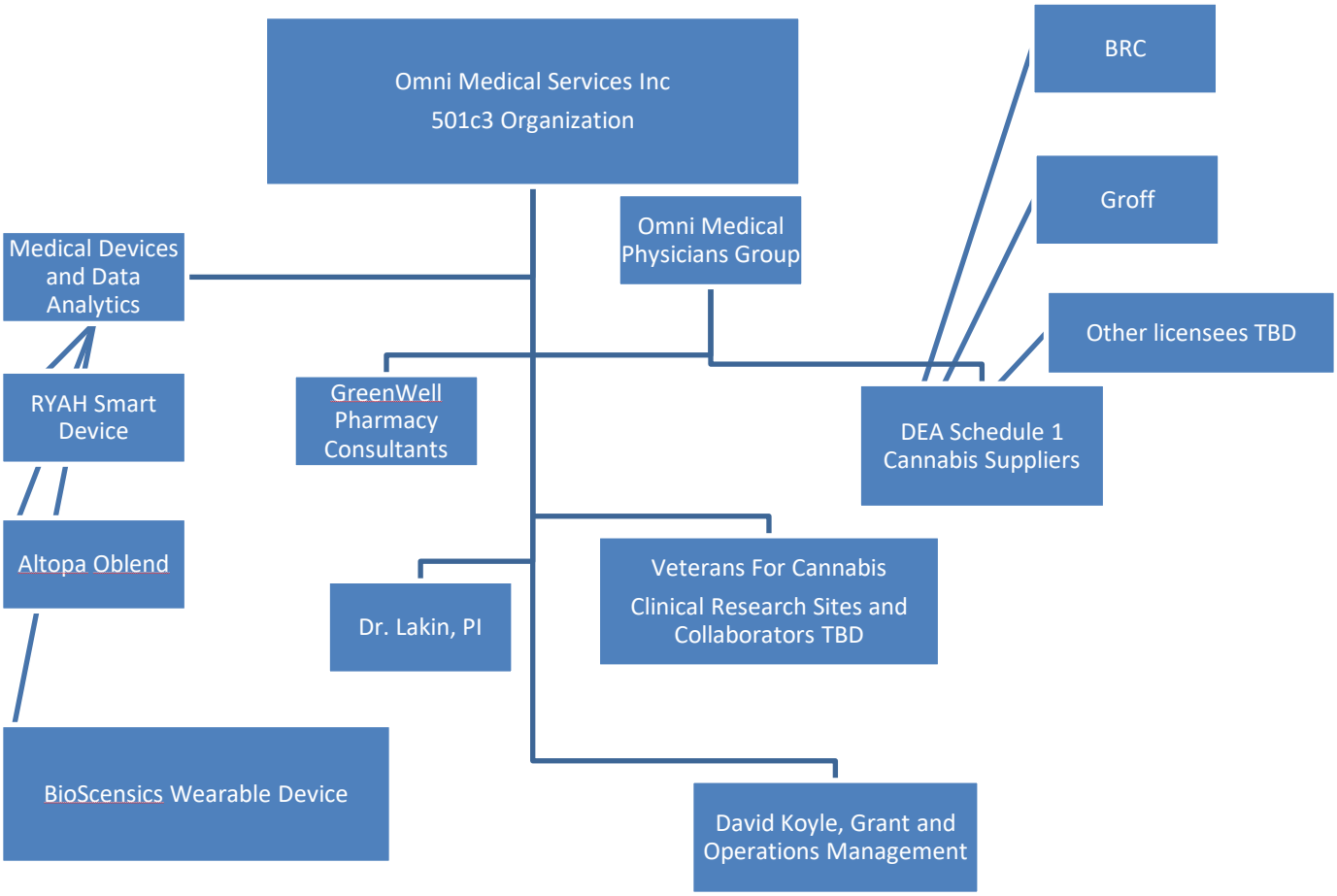
Attach a copy of your confidentiality agreement and provide a list of personnel and the date that the confidentiality agreement was signed.

BEGIN APPLICANT RESPONSE

Principal Investigator. Dr. Ryan Lakin, MD JD is a licensed physician who has been in practice since 2011. Dr. Lakin currently presides as medical director and board member of Omni Medical Services, Inc, a nonprofit 501(c)3 organization dedicated to research which will further the understanding of cannabis pharmacotherapies and their role in the medical management of various disease states. Dr. Lakin completed a clinical research fellowship at Cleveland Clinic/ Case Western in Ohio, and has presented at multiple national conference presentations and authored publications in scientific journals. Additionally, Dr. Lakin received his JD from the University of Toledo and is uniquely qualified to serve the role of PI for this program, as well as coordinating the administrative hurdles associated with cannabis and the FDA.

Grant Administrator. David Koyle is the founder of Omni Medical Services and has extensive experience in managing medical cannabis clinics for over 10 years in Oakland County. He has grown Omni's data base to over 20,000 medical cannabis patients since its founding in 2011. Omni now operates clinics in Michigan, Ohio, Illinois and Florida with plans for expansion into the Carolinas in 2023. Mr. Koyle served as an adjunct professor at Wayne State University for seven years. He has licensed new technologies from several universities' and successfully licensed these products and managed multi-million dollar budgets with Fortune 50 companies including Dow Chemical and Eastman Kodak. Mr. Koyle is a talented entrepreneur and creative leader with

an extensive portfolio of accomplishments in growing and optimizing diverse business products including commercializing the world's first digital sound on film for Eastman Kodak. He has presented technical papers at conferences in Germany, China, Japan, Canada and Washington and will act as the grant administrator and co-ordinate with the co-sponsors on the proposed research.



SIGNED CONFIDENTIALITY AGREEMENT

Representation Regarding the Prohibition on Using Funds under Grants and Cooperative Agreements with Entities that Require Certain Internal Confidentiality Agreements

By submission of its proposal or application, the applicant represents that it does not require any of its employees, contractors, or subrecipients seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting those employees, contractors, or subrecipients from lawfully reporting that waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information. Note that: (1) the basis for this representation is a prohibition in section 743 of the Financial Services and General Government Appropriations Act, 2015 (Division E of the Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. 113-235) and any successor provision of law on making funds available through grants

and cooperative agreements to entities with certain internal confidentiality agreements or statements; and (2) section 743 states that it does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

05/28/2022

_____ _____

Signature Date

END APPLICANT RESPONSE

V-H Budget

To enable the Issuing Office to evaluate all project costs, applicant(s) will submit a proposed budget and corresponding budget narrative. Please see attachment A for the required budget format. The budget and narrative must include only VMR grant funds in the budget; do not include matching, leveraged, cost share or any other type of supplemental funds. The budget narrative must identify the budget line item and number, provide a detailed description for each line, and include individual unit prices.

Selected applicant(s) will be required to provide supporting documentation for all grant expenditures incurred during the term of the grant. Accounting records must be supported by source documentation including, but not limited to, general ledgers, time sheets, payroll registers, invoices, check copies and bank statements, or cancelled checks. Expenses will be verified based on actual expenditures incurred within the grant period that are supported by source documentation, not budgeted amounts.

(1) Budget Changes – Any changes to the budget must be pre-approved by the Grant Administrator. Changes in the budget of less than 5% of the total line item amount do not require a formal amendment; however, a revised budget should be submitted to the Grant Administrator for approval. The allowable transfer should be calculated as less than 5% of the total line item that the funds are being transferred from.

Cumulative changes in the budget equal to or greater than 5% of the total line item amount may be permitted only upon prior review and written approval by the Grant Administrator. A formal grant amendment must be signed by both the grantor and grantee.

(2) Disallowed Costs – Disallowed costs include but are not limited to the following: sick pay, vacation pay, holiday pay, bonuses, overtime, tuition reimbursement/remission, vehicle allowance, seminars, conferences, meetings, subscriptions, dues, and memberships.

(3) Administrative Costs – Administrative costs cover expenses related to general administrative functions and coordination of functions and oversight related to VMR administrative functions. Administrative costs should include costs of goods and services required for administrative functions of the program; travel costs incurred for official business in carrying out administrative activities or the overall management of the VMR; costs of information systems related to administrative functions; and contractual services related to sub-recipients or vendors that are solely for the performance of administrative functions. **Total administrative and indirect costs must be identified, labeled clearly, and may not exceed 10% of the overall grant.**

(4) Budget Requirements – the proposed budget will display three (3) headings identified as the: Line Item, Budget Category, and Total. The budget line items that need to be included, at a minimum, are listed below. The budget should reflect the best estimate of actual costs using whole numbers. Please refrain from using decimals or formulas. Refer to the budget example provided in Attachment D.

- **Personnel** – In the budget, include the name, job title, and salary for each staff position to be paid for by the grant. Time sheets and payroll registers must be submitted for each staff position, and hours worked must be grantrelated. Fringe benefits may not exceed 35% of each employee's salary. Fringe benefits will be reimbursed based on actual expenditures per employee up to 35%, not on budgeted amounts. Allowable benefits include: health, dental, and optical insurance, employer-paid Social Security and Medicare tax, Michigan and Federal unemployment tax, and other miscellaneous fringe benefits (life insurance, long- and short-term disability insurance, worker's compensation, and retirement program contributions up to 4%). Applicant(s) must provide details on the organization's method of calculating fringe benefit expenses that will be charged to the grant including whether fringe benefits are calculated on an annualized basis or based on the length of the grant term.

  The budget narrative must include the number of weeks the individual will work on the grant; number of hours per week a full time employee of the organization is expected to work; a description of the work to be performed by each individual; the estimated hours to be worked; actual pay rate; the fringe benefit percentage being charged to the grant for each employee; the percentage of the employee's time allocated to the grant; whether each employee is salaried-exempt, salaried-non- exempt or hourly; and any other applicable information related to the individual's duties and responsibilities in

connection with this grant.

Individuals that are not on selected applicant(s)'s payroll, e.g., independent contractors, individuals receiving a Form 1099, temporary workers, etc., must be placed under the Contractual Services budget category. Only employees on the selected applicant(s)'s payroll should be included in the Personnel budget category.

- **Supplies, Materials, & Equipment:** specify item(s) and cost. The budget narrative should include the anticipated cost of each item, a detailed explanation of the item's purpose, and how it relates to the project being funded. Be as detailed aspossible.
- **Contractual Services:** these services must be competitively bid. Individuals that are not on selected applicant(s)'s payroll, e.g., independent contractors, individuals receiving a Form 1099, temporary workers, etc., must be placed under **Contractual Services**. When competitive selection is not feasible or practical, the selected applicant(s) agrees to obtain the written approval of the Grant Administrator before making a sole source selection. Selected applicant(s) must provide a copy of contracts, memoranda of understanding or agreements signed by selected applicant(s) and contractors.

  Selected applicant(s) assumes responsibility to select subcontractors on a competitive basis. A minimum of three (3) bids must be solicited and proposals must include, at a minimum: (1) name of selected applicant(s), grant number, and grant period; and (2) the type, number, and description of projects as described in the proposal.

  Selected applicant(s) must provide the Grant Administrator with the solicitation, list of vendor responses (including amounts), and name of the selected vendor. Selected applicant(s) must maintain bids on file at their place of business according to Section II-B, Records Maintenance, Inspection, Examination, Audit and Monitoring. The Grant Administrator will reserve the right to request a copy of all bids for services that are competitively bid.

  Selected applicant(s) must award the project to the lowest bid unless the Grant Administrator has given prior written approval for selection of a higher bid. Selected applicant(s) must provide a written justification for the selection of a higher bid. When awarding subcontracts, the selected applicant(s) must ensure that preference is given to products manufactured in or services offered by Michigan-based firms.
- **Travel:** in the budget include the name, job title and official workstation for each staff member that will be traveling. Selected applicant(s) must follow the State of Michigan Standardized Travel Regulations (www.michigan.gov/dtmb/0,5552,7-150- 9141_13132---,00.html). The State will reimburse for mileage, lodging, and meals, refer to the current State travel rates. Meals and lodging must be supported by itemized, legible receipts and reasons for travel. Itemized meal receipts must include a list of each item purchased; receipts for payments made by credit card that are not itemized will not be accepted.

  Mileage must be supported by travel log(s) with beginning and ending addresses, mileage total, and reason for travel. Grantees will be provided a travel log example. Out-of-state travel must be directly related to the grant project and approved by the Grant Administrator prior to travel. Travel expenses listed in the travel budget category are strictly for individuals listed on the budget under Personnel. Per Diem payments and alcoholic beverage reimbursements are not allowed.
- **Other Expenses:** This category is solely for use by organizations charging a per-case fee for work performed by subunits or internal agencies within the organization that do not require a competitive bid, i.e. contract, memorandum of understanding or any other type of signed agreement.
- **Indirect Costs:** Indirect costs are costs not directly or specifically related to the grant program. Indirect costs are costs of administering the organization and must be spread over a number of products, services, or grant programs proportionately. Examples include office

supplies and equipment, utilities, rent, maintenance and repair, insurance, accounting and bookkeeping services, and legal services. Non-cash expenses like depreciation, amortization, and depletion are not allowable indirect costs under this grant. **Total administrative and indirect costs must be identified, labeled clearly, and may not exceed 10% of the overall grant.**

Selected applicant(s) will be reimbursed for its proportional share of indirect costs. This means the MRA should be allocated a portion of the selected applicant(s)'s indirect costs and not 100% of the organization's total indirect cost.

Indirect costs should be displayed on the face of the budget on a single line item and the indirect rate should be rounded to six (6) decimal places. The budget narrative should contain a list of indirect costs, how the selected applicant(s) determined its indirect costs, and the percentage rate calculation for reimbursable indirect costs. Selected applicant(s) is not required to provide documentation supporting indirect costs; however, documentation verifying the costs must be retained by the selected applicant(s).

(5) To ensure efficient review and approval of grant expenditures, selected applicant(s) will be provided additional guidelines to assist with calculating and determining accurate and appropriate grant expenditures.

(6) Each budget category should have a subtotal displaying the total anticipated amount to be expended, and the budget should include a subtotal for total direct project costs and a sum of total project costs.

(7) After grants are approved by the MRA, modifications of proposals and budgets may be necessary. If the MRA does not approve the total amount requested in the original proposal, selected applicant(s) will be required to submit a revised proposal, budget and budget narrative for the purpose of entering into a Grant Agreement. New line items to the revised budget are not allowed.

(8) Selected applicant(s) assumes the responsibility of ensuring all unexpended grant funds are returned to the State of Michigan at the end of the grant period. Failure to do so may render selected applicant(s) ineligible for future grant awards and/or subject to legal action.

(9) Selected applicant(s) may not commingle grant award funds with current or future grant awards. All funding sources must be managed and accounted for separately.

BUDGET NARRATIVE
BEGIN APPLICANT RESPONSE

Budget Justification

Key Personnel (All personnel work 40-hr work weeks)

Dr. Ryan Lakin, MD JD, Principal Investigator, is a licensed physician who has been in practice since 2011. Dr. Lakin currently presides as medical director and board member of Omni Medical Services, Inc, a nonprofit 501(c)3 organization dedicated to research which will further the understanding of cannabis pharmacotherapies and their role in the medical management of various disease states. Dr. Lakin completed a clinical research fellowship at Cleveland Clinic/

Case Western in Ohio, and has presented at multiple national conference presentations and authored publications in scientific journals. Additionally, Dr. Lakin received his JD from the University of Toledo and is uniquely qualified to serve the role of PI for this program, as well as coordinating the administrative hurdles associated with cannabis and the FDA. He will provide overall scientific direction and coordinate the design, implementation, and quality control of data collected for the studies in this study. He will be responsible for all communication with the DEA, the DEA licensed suppliers, the FDA, IRB, and monitoring and reporting requirements, including filing annual reports under the FDA IND #156172 for cannabis. He will be involved in communications between the grant administrator David Koyle, and LARA/MRA. He will devote 40% effort, or 16 hours per week, to these clinical trials throughout the 2-year project period.

David Koyle, Grant Administrator, is the founder of Omni Medical Services and has extensive experience in managing medical cannabis clinics for over 10 years in Oakland County. He has grown Omni's data base to over 20,000 medical cannabis patients since its founding in 2011. Omni now operates clinics in Michigan, Ohio, Illinois and Florida with plans for expansion into the Carolinas in 2023. Mr. Koyle served as an adjunct professor at Wayne State University for seven years. He has licensed new technologies from several universities' and successfully licensed these products and managed multi-million dollar budgets with Fortune 50 companies including Dow Chemical and Eastman Kodak. Mr. Koyle is a talented entrepreneur and creative leader with an extensive portfolio of accomplishments in growing and optimizing diverse business products including commercializing the world's first digital sound on film for Eastman Kodak. He has presented technical papers at conferences in Germany, China, Japan, Canada and Washington and will act as the grant administrator and co-ordinate with the co-sponsors on the proposed research. As grant administrator, he will be responsible for any non-clinical aspects of the project. This includes regular communication with banking and accounting, coordinating with the medical device companies, the DEA grower accounting and transactions, and LARA/MRA. He will devote 50% effort, or 20 hours per week, to these clinical trials throughout the 2-year project period.

Fringe Benefits

Fringe benefits are calculated on requested salary. The fringe rates are set based on typical academic institution rates at 20-25%.

Cannabis Administration Expenses

Cannabis: THC and Cannabidiol (CBD)

We will purchase cannabis product in bulk from a license Michigan grower initially. After our DEA schedule I license to distribute cannabis to humans for research is obtained (anticipate summer 2023), we will purchase directly from one or more of the entities (GroffNA, BRC). We will allocate $1200 per Veteran per year to purchase cannabis. 300 total Veterans x $1200 x 2 years = $720,000, or $360,000 per year. We will purchase CBD preparations from Oblend for 200 total veterans. 200 Veterans x $500 x 2 years = $200,000 total funding for project.

Cannabis Vaporizers

We will purchase one RYAH Medtec vaporizer per veteran. This will be a one-time cost of $200. Cartridges can be re-used, but anticipated to be replaced from time to time at minimal cost. 300 total Veterans x $200 vaporizer + RYAH software/ data analytics = $120,000 total funding for project.

Wearable Technology

Biosensics will provide wearable devices for Veterans (devices will not be permanently given to Veterans due to cost of items), total for funding period is $100,000 for devices and data analytics.

All participants will be selected to receive a wearable device (Fitbit or Amazon Halo) to enable passive activity, sleep data collection, and cannabis consumption. We will purchase 300 devices at $350/device = $105,000 total funding for project.

DNA profiles

As part of the study, participants will submit a sample for genotyping using Endocanna's EndoDNA genomic testing platform. Results will inform the research team whether specific genetic profiles may correlate with treatment response. In addition, a biometric wearable device called the EndoLink BioStrap will be provided to each participant. All this data will be clustered and analyzed by Machine Learning Neural Network for Building Predictive Inferences. Costs will be 300 Veterans x $695 per test and EndoLink = $258,500 total funding for project.

Contractual Services

Omni Doctors, LLC

Omni has an extensive multistate clinical network of physicians with extensive experience in medical cannabis treatment for a variety of conditions. Our physician network will be implemented to handle the volume of telemedicine visits proposed in the project. Costs will be $100,000 per year x 2 years = $200,000 total funding for project.

Community Partners

Veterans for Cannabis will be paid $100,000 annually for recruitment, advertising, and scheduling of their list of veterans in the community. $100,000 x 2 years =$200,000 total funding for project.

Pharmacy consultants

GreenWell Consulting ($50,000/ year = $100,000 total project funding). Dr. Kelsey Echelbarger graduated from the Ohio Northern University Raabe College of Pharmacy with her PharmD in 2011. She has extensive and diverse pharmacy experience including hospital, retail, ambulatory care and dispensary management. Dr. Echelbarger specializes in cannabis pharmacotherapy and

palliative care and founded GreenWell Consulting to expand this work. Her practice and research focus on development of guided educational and medication therapy management programs to expand pharmacist practice and provide patients with access to quality care. Her experience in these areas has driven her to focus on the opportunities targeted, patient-directed pharmacotherapy-based interventions can have on outcomes in the management of complex disease states including chronic pain and substance use disorder.

Accounting Services

MLS+Co., P.C. will be performing our accounting services, including 3rd-party oversight and access to all grant funds, performing audits, and providing the necessary financial reports to remain in compliance with the grant requirements. ($25,000 per year x 2 years = $50,000 total funding for project). Letter of support included in Attachments.

BUDGET
BEGIN APPLICANT RESPONSE
-
Budget Form (Attachment A Is Below)
--
END APPLICANT RESPONSE

V-I Additional Information and Comments

Include in this section any other information that is believed to be pertinent but not specifically requested elsewhere in this RFP.

N/A

V-J Certification of Proposal

Please sign the proposal including the following language:

I certify that all information contained in the proposal is true to the best of my knowledge and belief, and that the organization is in compliance and agreement with all sections of the Request for Proposal. Failure to comply with grant terms may result in termination.

Certified by: 05/30/2022

Ryan Lakin, Project Manager, Principal Investigator
Omni Medical Services Inc

Date

ATTACHMENT A: VMR BUDGET
Submission Date: 05/30/2020
Selected Applicant's Grant Number: _____

Line Item	Budget Category	TOTAL
1	**Administrative Expenses**	
2	**Administrative Personnel (Grant Administration Staff)**	
3	*Salary*	
4	David Koyle, Grant Administrator	$122,000
5		
6	**Total Salary**	$122,000
7	*Fringe Benefits*	
8	David Koyle, Grant Administrator	$35,000
9		
10	**Total Fringe Benefits**	
11	***Total Administrative Personnel***	$157,000
12	**Administrative Supplies, Materials, and Equipment**	
13	General Office Supplies	$0
14	***Total Administrative Supplies, Materials, & Equipment***	$0
15	**Administrative Contractual Services**	
16		$0
17	***Total Administrative Contractual Services***	$0
18	**Administrative Travel (Grant Administration Staff)**	
19	Mileage	$0
20	Meals	$0
21	Lodging	$0
22	***Total Administrative Travel***	$0
23	**Total Administrative Expenses**	**$157,000**
24	**VMR Program Expenses**	
25	**VMR Program Staff**	
26	*Salary*	
27	Ryan Lakin, MD JD – Contact Principal Investigator	$145,200
28		
29	**Total Salary**	$145,200
30	*Fringe Benefits*	
31	Ryan Lakin, MD JD – Contact Principal Investigator	$35,000

32		
33	**Total Fringe Benefits**	$35,000
34	***Total VMR Program Staff***	$180,200
35	**VMR Personnel Program Staff**	
36	*Salary*	
37		
38		
39	**Total Salary**	
40	*Fringe Benefits*	
41		
42		
43	**Total Fringe Benefits**	
44	***Total VMR Personnel Program Staff***	
45	**VMR Supplies, Materials, & Equipment**	
46	Cannabis Administration Expenses (see attached justification)	$1,398,500
47	***Total VMR Supplies, Materials, & Equipment***	$1,398,500
48	**VMR Contractual Services**	
49	Contractual Services (see attached justification)	$550,000
50		
51		
52		
53		
54		
55	***Total VMR Contractual Services***	$550,000
56	**VMR Travel (VMR Staff)**	
57	Mileage	$0
58	Meals	$0
59	Lodging	$0
60	***Total EAP Travel***	$0
61	**VMR Other**	
62	Does not apply	$0
63	***Total EAP Other***	$0
68	**Total VMR Program Expenses**	**1,948,500**
69	**Total Direct Cost**	**$2,128,700**
70	*Indirect Cost (0.07)*	$157,000
71	**TOTAL PROJECT COST**	**$2,285,700**

ATTACHMENT B: REFERENCES

1. Bonn-Miller MO, Sisley S, Riggs P, Yazar-Klosinski B, Wang JB, Loflin MJE, Shechet B, Hennigan C, Matthews R, Emerson A, Doblin R. The short-term impact of 3 smoked cannabis preparations versus placebo on PTSD symptoms: A randomized cross-over clinical trial. PLoS One. 2021 Mar 17;16(3):e0246990. doi: 10.1371/journal.pone.0246990. PMID: 33730032; PMCID: PMC7968689.

2. Olenick, M., M. Flowers, and V.J. Diaz, US veterans and their unique issues: enhancing health care professional awareness. Adv Med Educ Pract, 2015. 6: p. 635-9.

3. Bonn-Miller MO, Brunstetter M, Simonian A, Loflin MJ, Vandrey R, Babson KA, Wortzel H. The Long-Term, Prospective, Therapeutic Impact of Cannabis on Post-Traumatic Stress Disorder. Cannabis Cannabinoid Res. 2022 Apr;7(2):214-223. doi: 10.1089/can.2020.0056. Epub 2020 Dec 9. PMID: 33998874.

4. Ilgen MA, Zivin K, Austin KL, Bohnert AS, Czyz EK, Valenstein M, Kilbourne AM. Severe pain predicts greater likelihood of subsequent suicide. Suicide Life Threat Behav. 2010 Dec;40(6):597-608. doi: 10.1521/suli.2010.40.6.597. PMID: 21198328.

5. Ilgen MA, Kleinberg F, Ignacio RV, Bohnert AS, Valenstein M, McCarthy JF, Blow FC, Katz IR. Noncancer pain conditions and risk of suicide. JAMA Psychiatry. 2013 Jul;70(7):692-7. doi: 10.1001/jamapsychiatry.2013.908. PMID: 23699975.

6. Ilgen MA, Kleinberg F, Ignacio RV, et al. Noncancer pain conditions and risk of suicide. JAMA Psychiatry. 2013;70(7):692-697.

7. Ilgen MA, Bohnert ASB, Ganoczy D, Bair MJ, McCarthy JF, Blow FC. Opioid dose and risk of suicide. Pain. 2016;157(5):1079-1084.

8. Maust D, Cristancho M, Gray L, Rushing S, Tjoa C, Thase ME. Psychiatric rating scales. Handb Clin Neurol. 2012;106:227-37. doi: 10.1016/B978-0-444-52002-9.00013-9. PMID: 22608624.

9. Weathers, F.W., et al., The Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). 2013, Washington DC: National Center for PTSD.

10. Weathers, F.W., Litz, B.T., Keane, T.M., Palmieri, P.A., Marx, B.P., & Schnurr, P.P. (2013). The PTSD Checklist for DSM-5 (PCL-5). Scale available from the National Center for PTSD at www.ptsd.va.gov.

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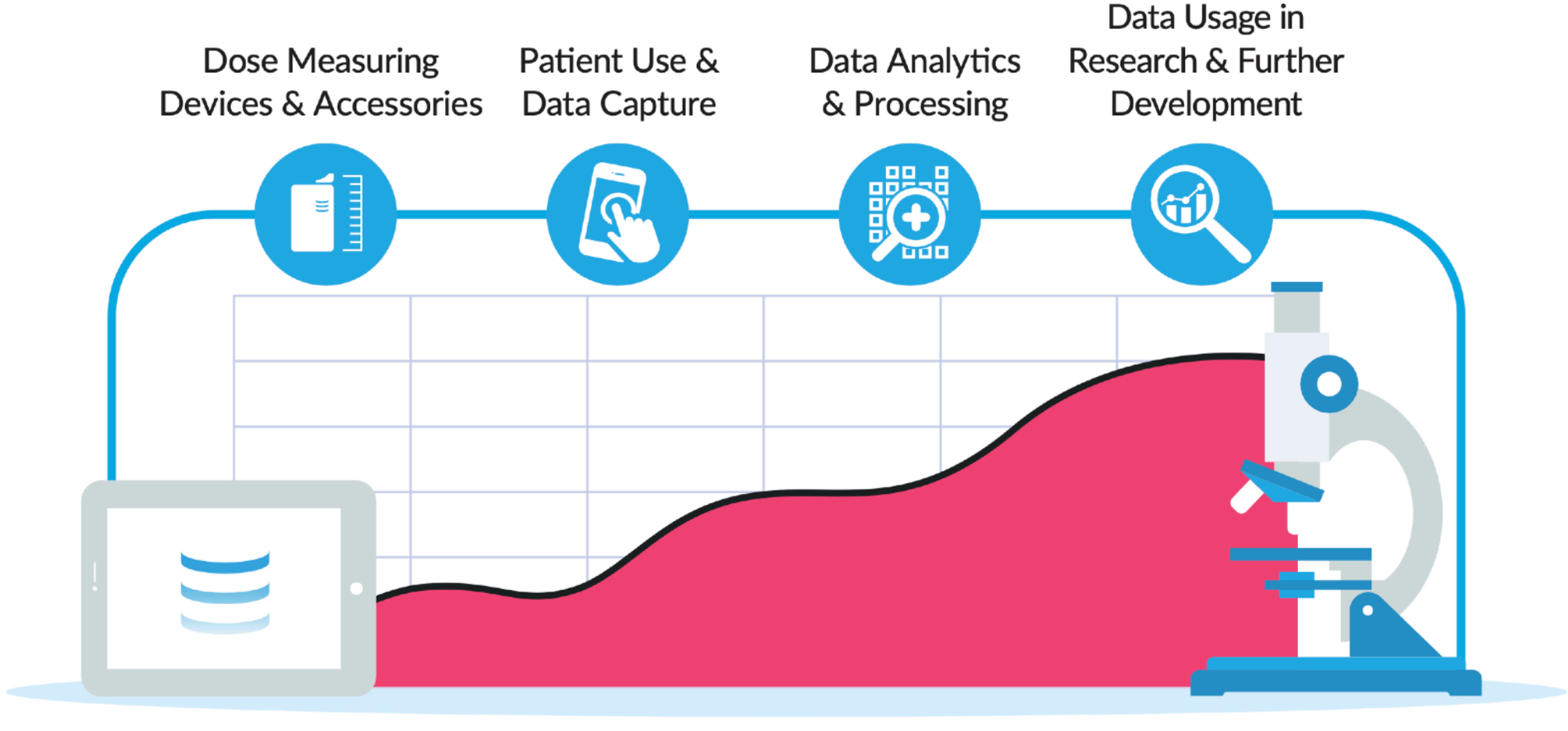
RYAH

You're in control

Target Market: Seed to Consumption

Working with different players in the ecosystem, RYAH powers multiple stages in the cycle of plant-based treatment and provides necessary tools to better understand user's behaviour and treatment effects



Clinical Trial Cycle

1

Clinic establishes partnership with RYAH

2

RYAH develops custom mobile app for the trial and provides devices and cartridges

3

Filling Partner fills cartridges with flower

4

Patients receive devices and medicine

5

Patients medicate with RYAH dose-measuring devices

6

Patients provide obligatory reviews via mobile app

7

HIPAA-compliant data is registered in backend

8

Data returns to clinic and filling partner for further use

RYAH Inhaler

Features and Functions

Even Heat Distribution
Cylindrical heating chamber evenly bakes the contents of the cartridge providing unparalleled flavor and consistent experiences

Airflow sensor
RYAH's airflow sensor records exactly how much you inhale to help you replicate the perfect session

Medical Grade Materials
RYAH uses high quality, materials to deliver a premium experience that keeps you healthy

Diffused mouthpiece
Extended pathway lengthens the vapor travel before reaching your lips, ensuring a pleasant draw at high temperatures

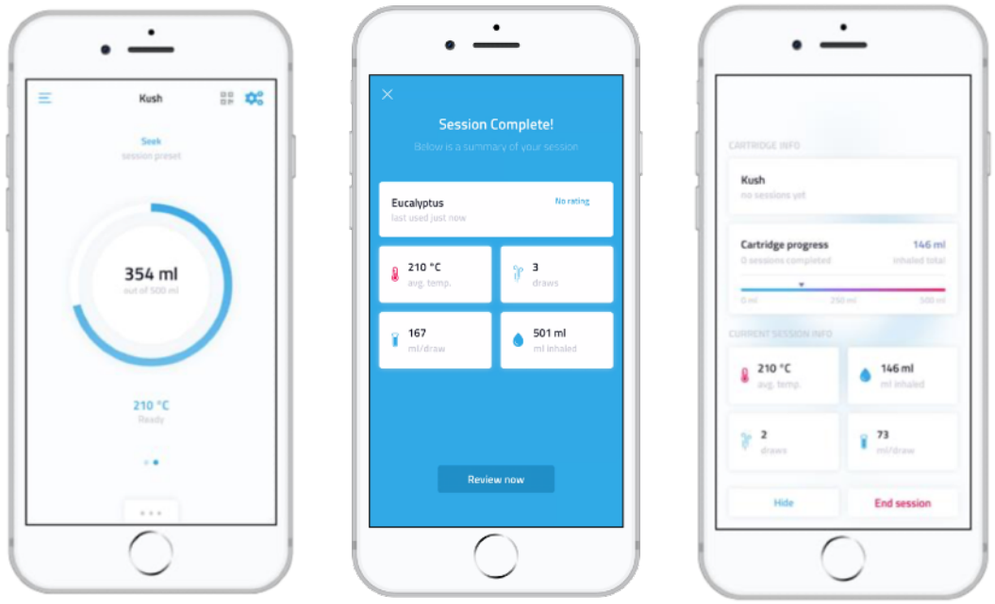
Replaceable Battery
Never be stuck with a dead device! Swap your battery for an instant charge when you're on the go

Easy To Clean
No turns in the heating chamber makes cleaning RYAH simple and intuitive

RYAH Inhaler

RYAH INHALER: MOBILE APP

- Scan cartridge QR
- Set precise temperature
- Track and control dose
- Record how you feel after each session
- App learns how each dose affects you
  - Can recommend the dose most likely to produce a specific mental/physical side effect
  - Can recommend the dose most likely to improve your medical condition



BioSensics™

Wearable Sensors and Digital Platforms for Clinical Trials, Patient Monitoring and Health Assessment.

- Founded in 2007 by 3 scientists from Harvard.
- Has received $40M+ of funding from NIH.
- In August 2019, Best Buy acquired predictive healthcare technology business of BioSensics.
- One of the recipients of 2020 Tibbett's Award from the U.S. Small Business Administration.

BioSensics develops and offers advanced technologies for collection and analysis of sensor-based and digital biomarkers and endpoints.

Digital Biomarkers (motor, speech and cognitive function)

Wearable sensors

Physical activity and posture

Falls

Gait and balance

Instrumented ADL

Motor symptoms (Tremor, chorea)

Upper extremity

Speech activity (early stage)

Digital

Cognition

Handwriting skills

Life space

motor control

Pattern tracing

Voice biomarkers

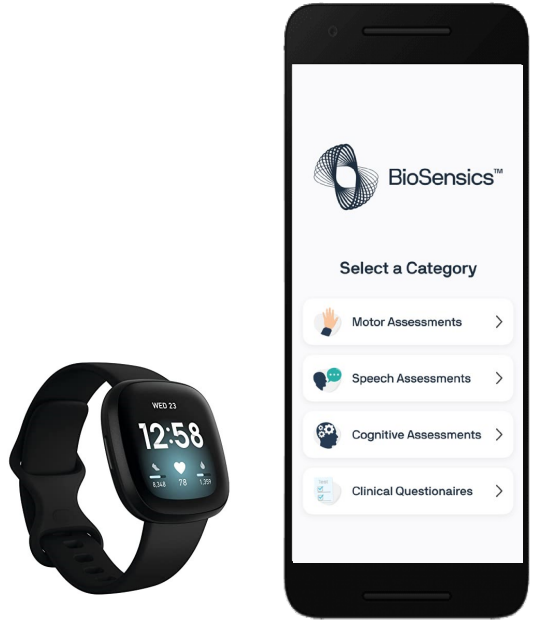
Video

Ptosis (early stage)

BioSensics products for clinical research and trials

BioDigit Home
continuous sensor monitoring, digital assessments and ePRO at patients' home.

BioDigit Clinic
Objective, centralized assessments during site visits using sensors and digitized tests.

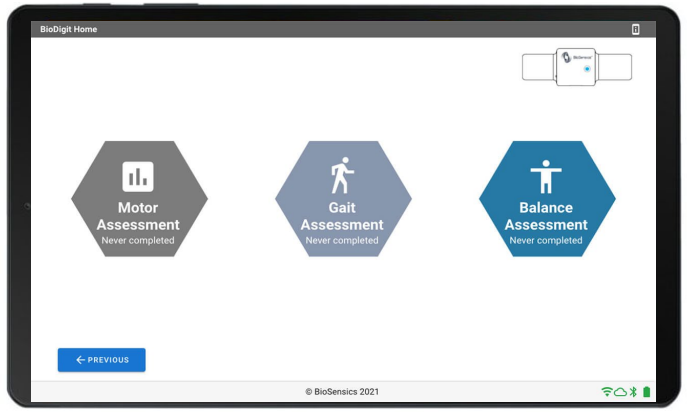


BioDigit Mobile
mobile health application for monitoring motor, speech and cognitive function.

BioDigit Home

A robust solution for collection of digital biomarkers from wearable sensors, mobile applications and digital technologies at patients' home.

Remote gait/balance measurements



LEGSys™

- Gait assessment
- Timed-Up-And-Go (TUG)
- Objective 6MWT
- Fall risk screening

Remote physiological monitoring

Thermometer

Spirometry

Blood Pressure/
Heart Rate

Remote trials

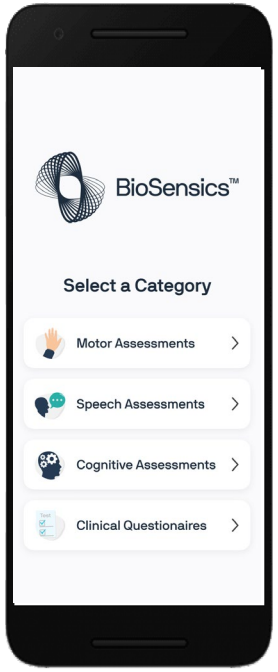
Audio and visual reminders

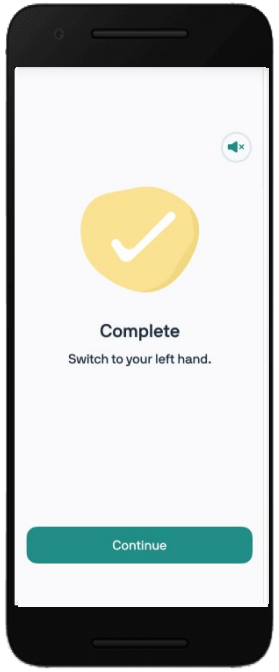
TeleCOA and virtual visits

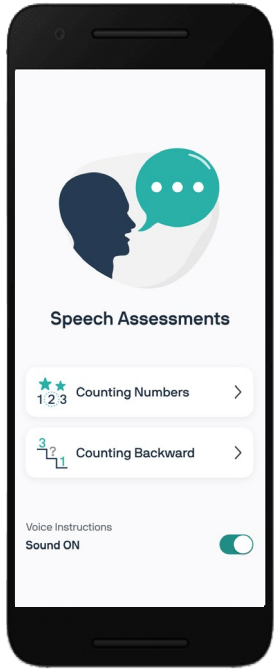
- Audio/visual reminders
- Virtual visits
- Medication diary
- Text notifications
- Study schedule

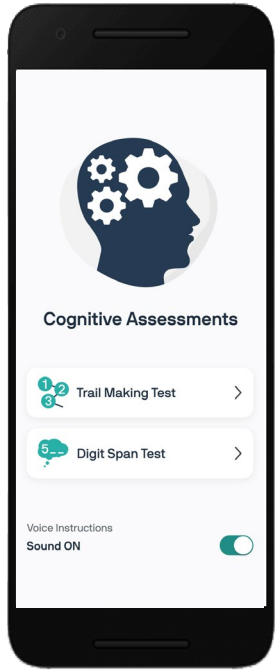
BioDigit Mobile

Mobile health application for monitoring motor, speech and cognitive function and mental health.









Fitbit is integrated (raw data collection)

Motor symptoms

Hand function

September 22, 2021

Biopharmaceutical Research Company (BRC)
C/o George Hodgin, CEO
11045 Commercial Parkway
Castroville, CA, 95012
Ghodgin@biopharmaresearchco.com
831-632-0913

OMNI Medical Services, Inc.
13 N Washington St
Ypsilanti, MI 48197

BRC Overview

We are a DEA-registered specialty pharmaceutical manufacturing firm focused on the production of botanically-derived cannabinoid products for DEA registered dosage manufacturers, drug developers, academic researchers and delivery-focused firms. BRC is in compliance with all federal mandates and retains 6 Schedule I registrations with the DEA to include: Import, Export, Researcher, Distributor, Manufacture (Bulk), and Analytical Lab.

FDA Botanical Drug Development Guidance Information

The following data is provided to aid in the development of IND Protocol submission. BRC is currently working toward our FDA API site registration and has begun development batches. We are targeting specifications below in support of this IND.

Botanical Raw Materials:

Description: Cannabis Sativa L. ground inflorescence
Description of Growth Conditions:
Propagation – 2 week duration. Light cycle of 18hr ON/6hr OFF and temperature of 20-26°C throughout. Plastic domes to maintain 100% humidity for the first 3-5 days, and tapered down to 60-70% humidity for the remainder of the 2 week period.
Vegetative – 1 week duration. Light cycle of 18hr ON/6hr OFF, temperature of 20-26°C, and 60% humidity throughout.
Flowering – 8-9 week duration. Light cycle of 12hr ON/12hr OFF, temperature of 18-25°, and 40-50% humidity throughout.

Description of Plant Growth Stage at Harvest: 8-9 weeks into the flowering period when cannabinoid and terpene content is at a maximum.

Description of Post-Harvest Processing: (e.g. washing, drying, grinding procedures)
Buds removed from stems at harvest time and “wet” trimmed with a trimming machine. Trimmed buds placed on drying racks and maintained at a temperature of 15-20°C and humidity of 60-65% for a period of 1-2 weeks. Cured in stainless steel containers with a humidity regulator for a minimum of 2 weeks before packaging.

Procedures for Control of Foreign Matter: Product inspected visually at all stages of growth, harvest, and post-harvest.

Description of Preservation Procedures:

-Handling – all product handled with sterile gloved hands.
-Transportation – all product will be handled with care and transported in a timely manner.
-Storage Conditions – packaged with nitrogen gas and vacuum sealed.

Botanical Identification (macro & micro):
Cannabinoid Potency: Targeting 20% THC / 5% CBD
Certificate of Authenticity: To be provided upon delivery of product
Certification of Impurities: To be provided upon delivery of product

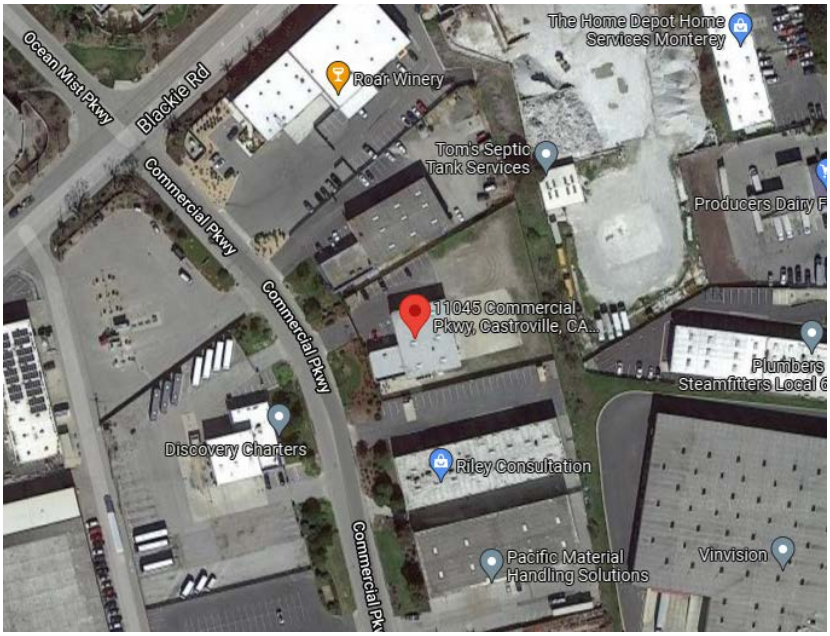
-Pesticides per USP 561
-Myco/Afltoxins per USP 561
-Elemental impurities per USP 232
-Microbial per USP 61/62
-Residual solvents per USP 467

BRM Grower/Supplier Information:

Name: Biopharmaceutical Research Company
Address: 11045 Commercial Parkway
Castroville, CA, 95012
Harvest Location: GPS (36.75855678292495, -121.74057485734937) See attached Appendix A.

DEA Schedule I (Bulk) Manufacture Registration - RB0600165 See attached Appendix B.

Appendix A.



Appendix B.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RB0600165	07-31-2022	$3047
SCHEDULES	**BUSINESS ACTIVITY**	**ISSUE DATE**
1	MANUF (BULK)	06-03-2021

BIOPHARMACEUTICAL RESEARCH COMPANY LLC
11045 COMMERCIAL PARKWAY
CASTROVILLE, CA 950123209

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

M L S + C O METZLER+LOCRICCHIO+SERRA+CO., P.C. CPAs + Tax + Financial Consultants

Member of American Institute of CPAs
Member of Michigan Association of CPAs

David C. Koyle
8068 Asher Chase Trail
Lancaster, SC 29720

Dear Dave:

As you requested and as you know, I, Michael A. Locricchio, CPA, and the certified public accounting firm of Metzler Locricchio Serra & Co have been prepared your yearly individual income tax returns and all related accounting and business services you have required since 1994.

We have been intimately involved with you with respect to you and your businesses tax, accounting and financial services over these past 28 years.

The certified public accounting firm of Metzler Locricchio Serra & Co was established in 1983 (almost 40 years ago). It is a full service CPA firm with approximately fifteen (15) professionals and approximately six (6) support staff.

I, Michael A. Locricchio, CPA, have practiced in the tax, accounting and financial services industry for going on forty-five (45) years. I am a licensed non-practicing Michigan attorney and a licensed practicing Michigan CPA.

If you have further questions, please contact me to discuss.

Very truly yours,

Michael A. Locricchio, CPA.

1800 West Big Beaver Road, Suite 100 • Troy, Michigan 48084-3531 • 248.822.9010 Office • 248.822.9030 Fax • www.mlscocpa.com

VETERANS FOR CANNABIS

HONORING VETERANS • SERVING PATIENTS • SAVING LIVES

We are very excited to offer our support and partnership with Omni Medical for a much-needed comprehensive study into efficacy of medical cannabis and how medical cannabis could potentially help our Veteran community. Veterans For Cannabis (VFC) has been conducting informal observational studies with Combat and Non-Combat Veterans in our organization for more than 7 years. Our studies span over 37 states and U.S. territory of Guam.

During this time period, as well as right up through today, we have seen thousands of Veterans lives improved with medical cannabis. The issue we have is that our analysis is all anecdotal and not accepted as hard data. Over the last 5 years we have also tried to obtain numerous grants that would allow us to fund a research program (double blind placebo-controlled study), but all were denied! I do not believe those denials were because our research parameters were inadequate, but because we could not get approval from the DEA.

That's why our group is so hopeful that our partnership and support for Omni Medical and their tremendous leadership and research team, will tip the scales for this grant to be awarded to Omni Medical, in the state of Michigan.

We have been begging and pleading with the Veterans Administration to allow our Brother's and Sister's to utilize cannabis through the VA system for almost a decade. Veterans For Cannabis has coordinated multiple trips to congress for some of our members. VFC arranged visits with each members elected representative and senators during the trip. During these trips, we were rarely awarded any quality time and sometimes those elected officials would not even see or meet with us. They are unwilling to even open dialogue with their constituents who are not only constituents, but Veterans. Veterans who have put their own lives on the line to protect their elected official's freedom (the same freedom which allows those elected officials to not have a conversation with our Veterans). The most often used excuse from congressional members (and state elected officials too) is that they "just don't have enough data", or "we need studies done".

Our Veterans For Cannabis members could not be more excited and proud to partner with Omni Medical to recruit Veterans for a truly robust and quantitative

medical cannabis study. VFC will educate and recruit 250 to 500 or more Veterans in the state of Michigan for this study.

I know as you all read this letter of support, that last line may cause an eyebrow to raise...maybe you thought, why educate? That answer comes down to 1 issue. Veterans do not understand medical cannabis. Veterans think they will lose their benefits if they utilize cannabis and are terrified that they will lose their livelihood. That's our job at VFC, that's what we pride ourselves on, being educators first and foremost!

I can unequivocally say that VFC will be able to properly educate Veterans on what this study could mean, (either positive or negative in regard to medical cannabis, because data does not lie), and why they should participate. We can show them the regulations which are black and white and explain they will not lose their benefits, so they will be more open to participate. VFC is made up of Veterans, and Veterans often trust our own over civilians. We will be able to gain the trust and support which is needed to accomplish this study. Above that, we can explain the "why". Why--because if we can save 1 Veterans life with the data from this study, then it makes it all worth it.

We must save lives and reduce the suicide rate in our Veteran community. It takes partnerships and support to accomplish this objective. That's why we are proud to stand shoulder to shoulder with our support behind and beside the Omni Medical team. When this study is completed, we will again schedule trips to our Nation's Capital where we will present the data to those elected officials so they have the data needed to save lives!

Joshua Littrell

JOSHUA LITTRELL,
COMBAT VETERAN USAF
FOUNDER & CEO
VETERANS FOR CANNABIS

INTERNAL REVENUE SERVICE
P. O. BOX 2508
CINCINNATI, OH 45201

DEPARTMENT OF THE TREASURY

Date: MAR 27 2020

OMNI MEDICAL SERVICES INC
1023 S CASS LAKE RD
WATERFORD, MI 48328

Employer Identification Number:
35-2656855
DLN:
29053301353009
Contact Person:
JOAN C KISER ID# 31217
Contact Telephone Number:
(877) 829-5500
Accounting Period Ending:
December 31
Public Charity Status:
170(b)(1)(A)(iii)
Form 990/990-EZ/990-N Required:
Yes
Effective Date of Exemption:
April 1, 2019
Contribution Deductibility:
Yes
Addendum Applies:
No

Dear Applicant:

We're pleased to tell you we determined you're exempt from federal income tax under Internal Revenue Code (IRC) Section 501(c)(3). Donors can deduct contributions they make to you under IRC Section 170. You're also qualified to receive tax deductible bequests, devises, transfers or gifts under Section 2055, 2106, or 2522. This letter could help resolve questions on your exempt status. Please keep it for your records.

Organizations exempt under IRC Section 501(c)(3) are further classified as either public charities or private foundations. We determined you're a public charity under the IRC Section listed at the top of this letter.

If we indicated at the top of this letter that you're required to file Form 990/990-EZ/990-N, our records show you're required to file an annual information return (Form 990 or Form 990-EZ) or electronic notice (Form 990-N, the e-Postcard). If you don't file a required return or notice for three consecutive years, your exempt status will be automatically revoked.

If we indicated at the top of this letter that an addendum applies, the enclosed addendum is an integral part of this letter.

For important information about your responsibilities as a tax-exempt organization, go to www.irs.gov/charities. Enter "4221-PC" in the search bar to view Publication 4221-PC, Compliance Guide for 501(c)(3) Public Charities, which describes your recordkeeping, reporting, and disclosure requirements.

Sincerely,

Stephen a. Martin

Director, Exempt Organizations
Rulings and Agreements