State of Michigan
Department of Licensing and Regulatory Affairs
Marijuana Regulatory Agency

VETERAN MARIJUANA RESEARCH (VMR) GRANT PROGRAM

2021

REQUEST FOR PROPOSALS

VETERAN MARIJUANA RESEARCH (VMR) GRANT

RESPONSE DOCUMENT

ESTIMATED TIMELINE	
Issue Date	June 1, 2021
Inquiries Due	June 11, 2021
Inquiries Response Posted	June 18, 2021
Proposals Due	July 16, 2021
Anticipated Start Date	July 30, 2021

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

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Multidisciplinary Association for Psychedelic Studies (MAPS)

3141 Stevens Creek Blvd #40563

San Jose, CA 95117

United States of America

FEIN: 59-2751953

Phone: 831-429-6362

Fax: 831-429-6370

0% of the organization is located in Michigan

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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

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Name: Drew E. House

Address: 8980 Snowy Owl Ln, Blaine WA, 98230

Phone: 415-922-0389

Fax: 831-429-6370

Email: Drew@maps.org

Experience with Finance & Grant/Contract Administration of Drew E. House:

- 2019 to 2020: Interim CFO for MAPS. Oversight for post award of Marijuana Research Grant from Colorado Department of Public Health and Environment. Original CMS Contract Number 16 FHHA 88230, Amendment 2016*3020 #5.
- 2014 to 2016: Interim Executive Director & CFO for Clear Path. Sponsored land mine victim assistance program. Oversight for pre and post award of US State Department Grants.
- 2012 to 2013: Senior Director of Finance, oversight for Research Finance and Sponsored Research for Seattle Biomedical Research Institute (merged with Seattle Children's Research Institute). Included NIH, DOD, State and private foundation Grants and Contracts for Clinical and Basic research.
- 2003 to 2012: Chief of Research Finance, Director of Business & Fiscal Operations, Seattle Children's Research Institute. Oversight for Institutional Research pre and post award finance portfolio for $70M sponsored research program including NIH, DOD, State and private foundation grants/contracts, including grants from the State of Washington for the Tobacco settlement and Seattle Children's Research Institute. From 2003 to 2010, oversight for Business and Finance Operations of the largest clinical research program at Seattle Children's (Cystic Fibrosis Foundation's Therapeutic Development Network, CFTDN) including pre and post award management for NIH R01's, U01's and a variety of private foundation grants and industry contracts.

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END APPLICANT RESPONSE

V-C Method for Addressing the Problem

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

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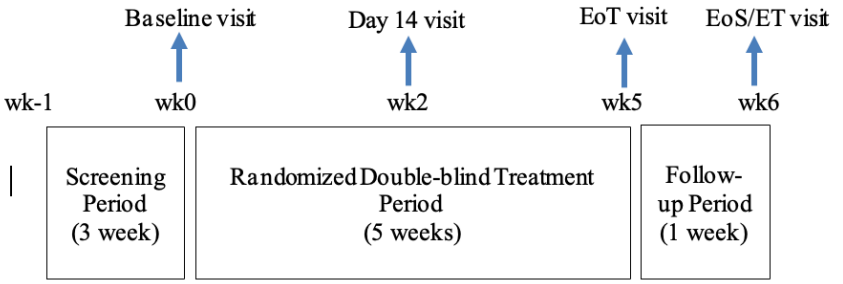
The Multidisciplinary Association for Psychedelic Studies (MAPS) is a 501(c)3 non-profit research and educational organization working as a clinical trial sponsor with the United States (U.S.) Food and Drug Administration (FDA) to obtain approval for the prescription use of botanical cannabis in patients with posttraumatic stress disorder (PTSD). MAPS has previously conducted the only FDA-regulated controlled study of cannabis for PTSD, funded with a $2.2 million grant from the Colorado Department of Public Health and Environment. The study enrolled 76 veterans with peer-reviewed results published in March 2021 in the open-source Public Library of Science (PLOS ONE).

The present study proposal aims to examine the use of inhaled cannabis containing High THC against placebo for treatment of PTSD among 360 veterans in an outpatient setting with a parallel design and methods to mitigate placebo response. The study will be conducted at 6 clinical trial sites in Michigan and other states in the U.S. The study will consist of a 3-week Screening Period, a 5-week randomized double-blind Treatment Period, and a 1-week Follow-up Period. This clinical trial is aligned with the grant program's goal of evaluating the potential of cannabis for treating medical conditions of U.S. armed services veterans and reducing veteran suicides, as PTSD, depression, and substance use disorders are significant drivers of suicidality in this population. The study design is illustrated below.

The study population will be military veterans ≥18 years of age with a confirmed diagnosis of moderate to severe PTSD from any cause with at least 6 months duration. Generalizability of study results will be ensured by including veterans with: (i) major depressive disorder in the absence of psychotic features, (ii) active suicidal thoughts and low risk of suicide attempts based on recent history, (iii) a history of alcohol or cannabis use disorder as long as they test negative for THC on a urine drug test. By including veterans who are experiencing significant predictors of suicide risk and monitoring these symptoms throughout, this study is designed to meet the objectives of this grant program and make the best case for researching the efficacy of cannabis in treating the medical conditions of U.S. armed services veterans and preventing veteran suicide.



EoT = End-of-Treatment; EoS = End-of-Study; ET = early termination; wk = week.

Participants will be recruited through the Veteran Administration (VA) network and Veteran Service Organizations as well as through a targeted recruitment website. Two of the clinical trial sites are VA sites and all researchers who are committed to this trial have extensive clinical research experience as demonstrated by the Letters of Support provided with this application. Furthermore, one VA and one private practice clinical trial site are located in Michigan.

This study will continue MAPS' investigation into the treatment of PTSD with the second randomized controlled trial (RCT) to test the therapeutic potential of inhalation of botanical cannabis as a treatment for PTSD in U.S. veterans. This study is essential for understanding potential risks and therapeutic benefits of cannabis for PTSD patients. The study protocol has already been submitted to and reviewed by the U.S. FDA, with some minor methodological design elements still under discussion. Unlike observational studies, which are not FDA or DEA regulated or approved, which study state legal but federally illegal marijuana, our study is an FDA and DEA-regulated double-blind, placebo-controlled RCT sponsored by a non-profit organization using federally legal cannabis. Our study is following all applicable regulations to obtain FDA approval for prescription use of cannabis in order to provide federally legal access to cannabis for veterans who are at risk for suicide, as stipulated by the law that defines this grant opportunity, with insurance coverage possible after FDA approval.

MAPS has dealt with and overcome significant regulatory obstacles coordinating and managing clinical research with cannabis over the last ten years in order to conduct the first RCT that was referenced in this RFP, "Placebo-Controlled, Triple-Blind, Randomized Crossover Pilot Study of the Safety and Efficacy of Four Different Potencies of Smoked Marijuana in 76 Veterans with Posttraumatic Stress Disorder (PTSD)." Obtaining approvals from FDA, DEA, Independent Review Boards (IRBs), National Institute of Drug Abuse (NIDA) Public Health Service were required in order to obtain a Letter of Authorization to access the Drug Master File owned by NIDA for the first RCT. The previous FDA and DEA requirement to use federally regulated cannabis obtained from the NIDA Drug Supply Program posed a significant barrier to research and limited the ability to progress to Phase 3 with the same cannabis supply. As many VA clinical trial sites were previously under the impression that conducting cannabis research was federally illegal, this precluded direct recruitment of veterans from VA networks. The MAPS-sponsored study conducted by Dr. Sue Sisley at the Scottsdale Research Institute in Phoenix, AZ produced published results from a grant-funded FDA-regulated RCT of botanical cannabis for treatment of PTSD.

Despite the aforementioned challenges, this study achieved the prespecified benchmarks for success, provided a more thorough understanding of the potential risks and benefits of marijuana as a treatment for PTSD, and informed the development of larger RCTs. All treatment groups showed good tolerability and improvements in PTSD symptoms after three weeks of treatment although the study failed to demonstrate a statistically significant difference between smoked cannabis preparations containing High

CBD vs. High THC vs. Balanced THC/CBD vs. placebo in regard to their impact on PTSD symptoms. The failure to differentiate treatment groups from placebo is likely attributable to the higher than anticipated placebo response, low quality and potency in the sole source of federally legal cannabis, limitations to statistical power introduced by testing various ratios of THC to CBD in one trial, and shorter than average duration of treatment in favor of maximizing participant retention. Higher powered studies including more participants, longer treatment duration, and methods to mitigate placebo response are warranted. Furthermore, the U.S. FDA has indicated to us that they are open to consideration of imported high quality flower cannabis which would more closely mirror what is available within state-regulated medical cannabis programs for this trial. MAPS has arranged for higher quality cannabis supply with reproducible composition and potency, as verified by consumer reports. The proposed study incorporates all of these trial design improvements and is well positioned to meet all objective benchmarks for success.

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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-bearing account.
- 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

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

The sponsor, MAPS, holds the Investigational New Drug (IND) file with the U.S. FDA as the sponsor for cannabis trials and is responsible for funding the clinical development program. The sponsor has delegated the primary responsibility of trial organization to its wholly owned subsidiary the MAPS Public Benefit Corporation (MAPS PBC), including designing, initiating, managing, coordinating, continuing, and concluding the clinical trials within the clinical development program and ensuring compliance with the highest standards of clinical research, study protocol, and federal/state regulations. MAPS PBC is tasked with maintaining the overall quality of study conduct as the research arm of MAPS. MAPS PBC contracts with independent institutions and private practice clinical trial sites to accomplish these goals. At the broadest level, MAPS PBC ensures sponsor oversight of safety issues and manages the conduct of the study in line with the study budget.

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.

The MAPS PBC GxP Quality Manual defines the quality control roles, responsibilities, policies, and principles for the GxP functions executed by its employees and contractors. It also describes MAPS PBC's commitment to high product quality, safety, and efficacy standards, as well as its commitment to the following documents as applicable:

- World Health Organization (WHO) standards.
- International Conference on Harmonization (ICH) Guidance.
- United States Food and Drug Administration (FDA) GxP regulations, including Good
- Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice
- (GMP), and Good Documentation Practice (GDP) and Computer Systems Validation
- Applicable global regulatory requirements

The GxP Quality Manual also describes MAPS PBC's dedication to developing investigational and commercial products through ethical and compliant business practices. It includes the principals by which MAPS PBC strives to ensure its vendors adhere to quality standards consistent with those of MAPS PBC. MAPS PBC is a virtual company that does not manufacture, package, test, or store any investigational or commercial products on site. All manufacturing, packaging, testing, storage, and distribution activities are outsourced to qualified vendors. In addition, MAPS PBC utilizes various IT, GLP, and GCP vendors during the clinical development process.

Executive Management is responsible for establishing the organizational structure, resource allocation, and development of guidelines that assure Quality System implementation that support its effectiveness and conformance to regulatory requirements. Executive Management defines, approves, and supportsthe strategies, investment policies and budgets that assure the maintenance of the Quality System. Levels of authority are defined for managers and personnel to assure the provision of adequate resources. Executive management supports implementation of a Quality System that enables MAPS PBC to manage quality throughout all stages of the clinical trial process.

Executive Management provides evidence of its commitment to the development and implementation of the Quality System and maintaining its effectiveness by communicating to the organization the importance of meeting statutory and regulatory requirements, participating in and supporting execution of quality and compliance strategies and plans, ensuring that Quality Objectives are established, conducting Executive Management reviews, addressing serious GCP breaches as required, ensuring that all escalated compliance issues are remediated, as appropriate, and fostering continuous improvement, and ensuring that all applicable policies are implemented, or that a plan is developed and executed for expeditious implementation, and that the plan is monitored until all policies are implemented.

MAPS PBC outsources the Quality Assurance Unit (QAU) to the 2Richards, Inc. who define the company's quality policies and procedures. The independent QAU is responsible for compliance oversight and communicating requirements per FDA and ICH GxP guidelines to the Chief Executive Officer.

MAPS PBC will select and qualify a subcontracted Contract Research Organization (CRO) through a competitive bidding process following MAPS PBC Standard Operating Procedures. The CRO will provide training and supervision to clinical trial site teams, provide the study drug, monitor the data quality and integrity, ensure regulatory files are created and maintained, and safety reporting is conducted per GCP and regulatory requirements. The CRO will develop and implement the Monitoring Plan, provide study drug & oversight of Schedule 1 drug accountability, and site start-up, activation, and close-out. MAPS PBC will provide configuration and system administration and validation in a central Title 21 CFR Part 11-compliant Electronic Data Capture (EDC) and electronic Trial Master File (eTMF) systems, in order to collect and manage study data and essential regulatory documents in a manner that will pass regulatory inspections. MAPS PBC and the CRO will manage enrollment targets and facilitate discussions with Medical Monitors and Site Principal Investigators about inclusion/exclusion, protocol deviations, and safety. The study will be managed in line with Quality Assurance auditing procedures that are applied to all MAPS PBC research programs.

Investigators, therapy teams, and all study staff will be trained prior to study start by the CRO and MAPS PBC personnel on the protocol, procedures, safety considerations, and infrastructure. In addition, due to the placebo response rate observed in the first RCT of cannabis for treatment of PTSD that was previously published (Bonn-Miller et al. 2021), MAPS PBC has obtained a proposal from Analgesic Solutions, Inc. to provide Placebo Response Reduction and Accurate Symptom Reporting Training to clinical trial site staff and study participants through a Learning Management System. This proposal represents a comprehensive risk mitigation service taking a hands-on systematic approach to the trial.

The clinical trial sites will recruit & treat patients and complete remote data entry into the eCRF database. Throughout the study, the CRO personnel will meet regularly with the Investigator and/or site staff, monitor data remotely and periodically conduct in person routine monitoring visits, as appropriate for the rate of enrollment to comply with GCP guidelines and to ensure validity of study data. During each monitoring visit, the CRO personnel will perform source data verification to ensure compliance, including accurate and complete recording of data on eCRFs, source records, and drug accountability records. An eCRF casebook will be completed for each participant enrolled within the eCRF system. The CRO overseen by MAPS PBC will ensure the database is auditable at any time. All key personnel will be involved in final data clean up and database lock. A qualified MAPS PBC statistician will perform data analysis with input and review from key personnel. Close out visits will be performed at the site and the Data Science Team will manage the analysis and the Final Clinical Study Report process to complete FDA reporting requirements and publish the findings from this trial.

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.

The sponsor, MAPS, holds the IND for Cannabis and is responsible for securing funding for the clinical development program. MAPS' primary responsibility is to provide fiscal control and financial accounting procedures that the grant funds will be utilized with full accountability to ensure all expenditures charged to the grant are specifically allocable to the grant. Grant funds will be tracked via QuickBooks software using a unique class identifier tracking both income and expenses. Administrative financial staff at MAPS will include a bookkeeper, financial controller, and program accountant who will provide the effort to maintain and administer the extra records and accounting necessary to manage the program requirements. The reporting for this grant will be on a modified cash basis. Funds will be maintained in a non-interest-bearing operating account. MAPS performs an annual external financial audit. MAPS does not currently meet the financial threshold of Federal funding necessary to perform a Single Audit as required by OMB Circular 200.36 (A-133 Audit). Included in this application is a copy of MAPS' most recent audited financial statement.

4. Describe your agency's data security plan.

Information Technology (IT) is an integral and critical component of the applicant's daily business. The applicant has a comprehensive information security policy based on the NIST CSF v1.1 framework which describes IT practices. The MAPS PBC IT Steering Committee is responsible for review and enforcement of this policy. This policy seeks to ensure IT resources efficiently serve the primary business functions of the company, provide security for personnel and donors' electronic data, and comply with all applicable regulations. IT resources include hardware (mobile, desktop, server, and peripherals), software (line-of-business applications, general-purpose applications, operating systems), network equipment (routers, firewalls, wiring), and IT personnel. The integrity of all IT resources is extremely important to the successful operation of MAPS business. All computer equipment, peripherals, and software are the applicant's property and are provided for business purposes. Proper use and control of computer resources is the responsibility of all employees. Intentional or reckless violation of established policies or improper use of company computers will result in corrective action up to and including termination. Employees should also be aware that any work completed on company computers is subject to monitoring and review, and communications are not expected to be private. It is the policy of the company to use IT resources in a cost-effective manner that safeguards member data and promotes accuracy, safety, information, and efficiency. Whenever possible, technical controls enforce the applicant's policies and procedures such as automated software deployment, patch management, vulnerability scanning, asset management, and security awareness training. The overriding goal of this policy is to comply with all applicable regulations and to protect the integrity of the private and confidential member and business data residing within the applicant's technology infrastructure. Violation of any of these policies may result in disciplinary action which may include termination for employees and contractors; a termination of employment relations in the case of contractors or consultants; or dismissal for interns and volunteers. Additionally, individuals are subject to loss of company Information Systems access privileges and may be subject to civil and criminal prosecution. MAPS PBC maintains Standard Operating Procedures (SOPs) which supplement the information security policy and describe the procurement, provisioning, maintenance, and validation of information systems specifically utilized in the applicant's clinical research.

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END APPLICANT RESPONSE

V-E 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

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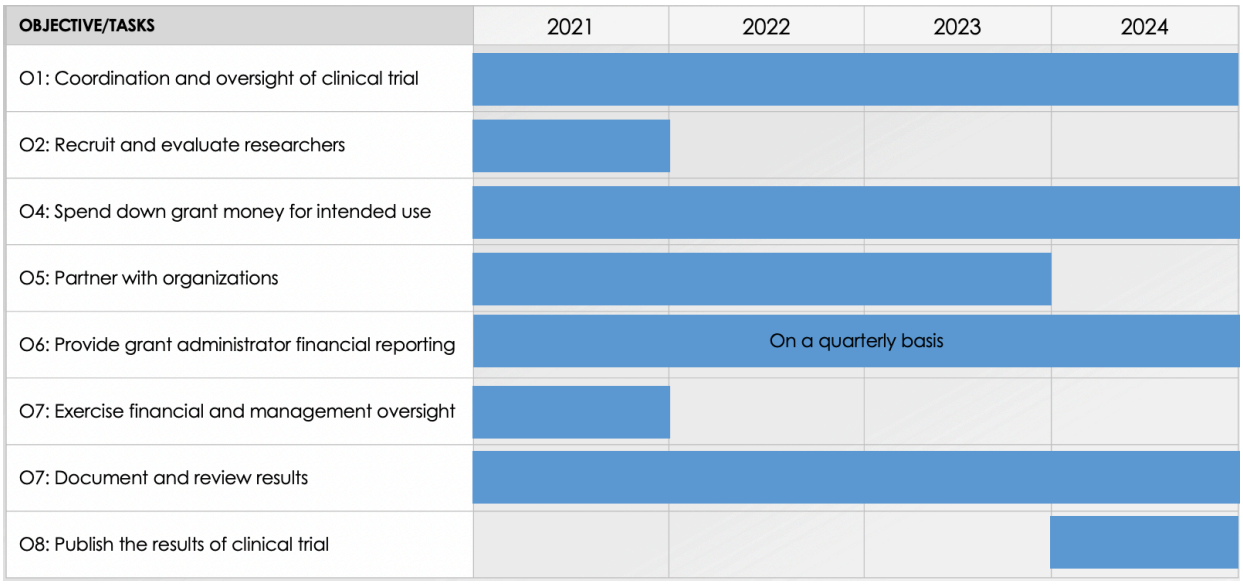
This study will begin August 1, 2021 and continue through June 2024. Below is a chart that demonstrates when the MAPS team will achieve grant objectives listed under “tasks” by grant year and detailed work plans for each objective.



Objective 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 multi-site study will be conducted at 6 clinical trial sites with 2-4 sites in Michigan and 2 sites outside Michigan. All clinical trial sites will have the ability to recruit veterans, either through VA networks or Veteran Service Organizations. CRO personnel will qualify and activate the clinical trial sites for this study. CRO personnel will prepare and conduct an Investigator Meeting with input from WCG Analgesic Solutions trainers on Placebo Response Reduction and Accurate Symptom Reporting Training. MAPS PBC personnel and clinical trial site personnel will also attend the central Investigator Meeting for training on the protocol, procedures, safety considerations and infrastructure. CRO personnel will visit all sites to ensure site readiness and training prior to study commencement. Each site will be equipped with laboratory space for conducting patient interviews and laboratory assessments, and a dedicated indoor smoking chamber with an air filter that allows for the administration of smoked cannabis. All cannabis will be packaged by a qualified, licensed facility and will be shipped to clinical trial sites for storing and dispensing according to DEA requirements. The clinical trial eligibility criteria are designed to be focused on recruiting veterans with mild to moderate risk of suicide and will include measures to monitor and measure suicide risk during the trial. The study protocol includes safety plans to assist clinical trial site staff in managing suicide risk during the study. The collaborative structure of this multi-site study will be established to ensure uniformity across sites. Throughout the study, the CRO will meet regularly with the Investigators, and CRO personnel will continuously monitor data remotely and conduct at least 78 in person routine monitoring visits. All sites will complete remote data entry into a centralized FDA compliant electronic database. The CRO will ensure the database is auditable at any time. MAPS PBC and CRO personnel will participate in final data clean up and database lock. The Director of Biostatistics will conduct data analysis with input and review from the CRO Biostatistics personnel. Close out visits will be performed by CRO personnel at each site and MAPS PBC and the CRO will jointly manage the Final Clinical Study Report process to ensure reporting as required by FDA and publications in peer-reviewed scientific journals.

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

MAPS PBC has already identified 4 of 6 potential clinical trial sites, including 2 Michigan clinical trial sites. The Michigan sites are the Ann Arbor VA and a Detroit private practice site led by Principal Investigator Dr. Annas Aljassem, MD, MHSA who has ties to both the Detroit VA and the Ann Arbor VA. Additional clinical trial sites represented in this application include the James A. Haley VA Medical Center in Tampa, Florida and the Scottsdale Research Institute in Phoenix, Arizona. Each Site Principal Investigator has adequate staff to support the study activities and will be responsible for study oversight and ensuring compliance of their respective sites with the study protocol and all applicable requirements. MAPS PBC and the CRO will be responsible for project management, data monitoring and storage, drug accountability, and ensuring regulatory files are created and maintained per Good Clinical Practice (GCP) requirements. VA-trained independent raters, not part of any site team or MAPS or MAPS PBC, will be responsible for administering the primary outcome measure (CAPS-5) at the Baseline and primary endpoint to minimize bias during the trial. Please refer to the Personnel section for more information.

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

MAPS was founded in 1986 with the mission of developing medical, legal, and cultural contexts for people to benefit from the careful uses of psychedelics and cannabis. MAPS has a long history and track record of success demonstrating the ability to work with researchers who can garner the U.S. FDA approval for clinical trials of Schedule 1 controlled substances such as cannabis and MDMA, with MAPS currently conducting FDA, Health Canada and Israeli Ministry of Health-approved Phase 3 research into MDMA-assisted therapy for PTSD. Per Title 21 CFR Part 312, sponsors are responsible for selecting qualified investigators, providing them with the information they need to conduct an investigation properly, ensuring proper monitoring of clinical trials, ensuring that the trial is conducted in accordance with the general investigational plan and protocols, maintaining an effective IND with respect to the clinical trials, and ensuring that FDA and all participating investigators are promptly informed of significant new adverse events or risks with respect to the investigational drug. MAPS has delegated sponsor responsibility to its wholly owned subsidiary MAPS PBC since it was founded in 2014.

Objective 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.

MAPS is dedicated to maximizing grant dollars used to coordinate and oversee this clinical trial. The total project cost is $17,583,994; indirect costs amount to no greater than 10% of direct costs. The MAPS Board of Directors also limits indirect costs to 10% of direct costs, and this requirement flows through to subcontractors of MAPS PBC. Administrative costs are further limited by design through operating both MAPS and MAPS PBC as completely virtual companies. All employees and contractors work from home and both companies do not have physical offices. As such, administrative staff do not incur travel costs for company business. MAPS and subsidiaries have found that operating virtually has provided numerous efficiencies and this is expected to continue through the grant period. See our budget for more details.

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

Participants will be recruited through the Veteran Administration (VA) network and Veteran Service Organizations as well as through a targeted recruitment website. Two of the clinical trial sites are VA sites and all researchers who are committed to this trial have extensive clinical research experience as demonstrated by the Letters of Support provided with this application. Furthermore, one VA and one private practice clinical trial site are located in Michigan. Two additional sites will be identified for this trial in Michigan to ensure that grant priorities are satisfied with Michigan firms. MAPS PBC will work with organizations closely tied to veterans and veterans' programs. Clinical trial sites will be responsible for obtaining local VA and/or IRB administrative approvals for study conduct, identifying veterans with PTSD, conducting screening, dispensing and disposing of study drug, supporting

participants during the treatment period, tracking and reporting all adverse events that occur during the trial, conducting follow-up visits per the study protocol.

1. The VA Ann Arbor Health System (VAAHS) in Ann Arbor, Michigan will be one of six sites participating in this clinical trial. The facilities and resources available at the VAAHS and its academic affiliate, the University of Michigan (UM), will provide Dr. Silveira and her investigative teams with an optimal environment for conducting pain research in cancer patients. The VAAAHS has the patient population and research infrastructure necessary to recruit the subjects required and conduct the study proposed. The UM has the equipment and experienced staff necessary to gather the data necessary to test the hypotheses proposed. The study team includes Dr. Silveira who is a world-class expert in palliative medicine and symptom science, as well as a seasoned primary care provider who has dedicated the last 21 years of her career to caring for Veterans. The VAAAHS is a complex tertiary referral facility that provided care to more than 65,000 veterans residing in Michigan and northwest Ohio in fiscal year 2015. The VAAAHS includes comprehensive medical, surgical, and psychiatric care as well as advanced diagnostic services such as positron emission tomography (PET), magnetic resonance imaging, cardiac catheterization and electrophysiology, nuclear medicine imaging, and interventional angiography. The main hospital campus located in Ann Arbor, Michigan, serves as a referral center for specialty care and operates 102 acute care beds (including 14 ICU beds) and 40 Community Living Center (extended care) beds, with more than 6,300 inpatient episodes of care provided in the hospital and extended care center in fiscal year 2015. Approximately 900 medical students, residents, and fellows train at the VAAAHS annually.

   The Ambulatory Care Clinic at the VAAAHS serves Veterans of varied sociodemographic backgrounds who live throughout Michigan, in urban, suburban, and rural settings. In FY 2013, the AAVAMC served 17,873 primary care patients: 5.9% female, 50.8% married, 43.6% white, 5.1% African American, and 0.5% Hispanic. The mean age of primary care patients is 64. Approximately 13.5% of Veterans have symptoms of PTSD. Veterans are routinely screened in ambulatory care for depression, anxiety, and military service-related trauma; hence facilitating the identification of Veterans with PTSD. Ambulatory care clinics have embedded mental health social workers who are available to formally evaluate Veterans with positive mental health screens. Mental health social workers in the VAAAHS are knowledgeable of all the services available through the VA to support Veterans with PTSD, including but not limited to psychotherapy and psychiatry services.

   The VA Ann Arbor Research Service is affiliated with the world-class research university, the University of Michigan. The VA Ann Arbor Research Service has a forty – seven thousand square foot dedicated research facility and over 150 research investigators with approximately 400 open studies at any time. The VAAAHS Research Service encourages and supports research investigations that have the potential to impact on the health and well-being of our nations Veterans. The Research Service is part of the VAAAHS a 109 acute-care bed facility that served over six-five thousand Veterans in fiscal year 2014, drawing from residents of Michigan and Northern Ohio. VAAAHS had 5,529 inpatient stays and 580,200 outpatient visits in fiscal year 2014.

2. James A. Haley VA Medical Center (VAMC) in Tampa, Florida will be one of six sites participating in this clinical trial. The Haley VAMC is one of the largest VA in the network and sees over 12,000 Veterans with PTSD on an annual basis. Many of these Veterans are willing to participate in clinical trials to help alleviate the various ailments that afflict them. If needed, the Bay Pines VA Healthcare System (<15 miles from the Haley VAMC) and the Orlando VA Healthcare System (<90 miles) both have very active hospitals and will provide referrals for recruitment to the study. The clinical site team has extensive contacts within the VA with a number of groups and physicians that support and care for Veterans with PTSD. Regular progress meetings will occur as needed based on recruitment. For identification of patients the team uses an all-inclusive screening method that leverages the VA database, identifying all potentially eligible patients by diagnosis, procedures and treatments, along with any other inclusion/exclusion criteria. Once identified, along with the waiver of HIPAA for screening, the site team will collect their contact information. This info is used to identify their provider, who can reach out directly, should they be willing, and also allows us to send out invitation/recruitment material via USPS mail or encrypted e-mail. Adam Zoble (research coordinator) has worked for 14 years in clinical research at James Haley VAMC. He has been involved with approximately 70 human trials and has experience in Phase I-IV pharma, device trials, emergency open label extension, HSR&D, CSP, CSR&D, NSF and multiple Operation Warp Speed COVID trials. The Haley VAMC site has been the top enroller on a number of occasions and most recently were #1 VA recruiter for the J&J Vaccine trial.

Almanac Cohort Diagnoses by Source

	FY19	FY20	FY21
POST-TRAUMATIC STRESS DISORDER	10,866	12,157	12,154

Almanac Cohort Diagnoses by Source

	FY19	FY20	FY21
(F43.10) POST-TRAUMATIC STRESS DISORDER, UNSPECIFIED	4,633	5,100	4,437
(F43.11) POST-TRAUMATIC STRESS DISORDER, ACUTE	31	43	30
(F43.12) POST-TRAUMATIC STRESS DISORDER, CHRONIC	8,122	9,138	9,449

3. Veterans Alliance for Holistic Alternatives is Veterans Service Organization headquartered in Gretna, Louisiana whose mission is to support veterans nationwide will be a partner with MAPS to help refer eligible veterans to the clinical trial. This organization will work closely with Dr. Sisley's site to refer veterans to her site as they have done for the first RCT in veterans conducted at Scottsdale Research Institute.

4. The cannabis processing and packaging and the cannabis inhaler will be provided by Syqe Medical. Syqe Medical is a med-tech company developing technologies that enable precise delivery of a wide range of therapeutic molecules via inhalation. Utilizing its novel technology, Syqe Medical® aims to relieve the suffering of as many patients as possible in the fastest possible way. The revolutionary Syqe drug delivery technology now allows hundreds of existing and preclinical drug molecules to be considered for inhalation, significantly changing their clinical profile and serving significant unmet needs. Syqe holds over 100 granted patents globally on its drug delivery platform. The Syqe® Inhaler is the first medical grade metered-dose cannabis inhalation delivery system meeting pharmaceutical standards. It is a single-patient, portable, multi-dose, hand-held device designed to precisely aerosolize and guarantee absorption of the target drug. During a two-second aerosolization, initiated by breath-actuation, the device engages automatic thermal and motorized flow controllers that ensure the delivery of aerosol into the lungs, independent of the inhalation pattern of the individual patient. Subsequently, the device requires minimal inhalation training. The device has undergone pharmacokinetic, pharmacodynamic and cognitive clinical trials, published in the scientific literature. Today the Israeli Ministry of Defense (MOD) provides veterans full reimbursement for the Syqe treatment (Inhaler and cartridges). The official reimbursement approval was given on May 11th, 2021 after a pilot program that was conducted with 30 patients and showed promising preliminary results (as part of Syqe's PMS program). Most of the patients suffer from chronic pain and PTSD. An Israeli veteran who survived a serious IED blast while on duty and subsequently suffered from chronic pain for the majority of his life stated, "The inhaler made it possible for me to breathe again. To be with people. To live. It's what caused the biggest improvement in my condition in decades," after trying the Syqe inhaler. This inhaler will be tested and compared to a placebo control in the proposed trial.

5. The cannabis for this trial will be provided by Aqualitas, Inc., a private company located in the community of Brooklyn, just outside of Liverpool, Nova Scotia. Home to Canada's 2020 Grower of the Year and Canada's first Clean Green Certified cannabis producer and processor, the Aqualitas commitment to international organic management practices, continued compliance, and world class quality and sustainability run deep. With a mission of supporting wellness through research, care and passion, Aqualitas is committed to being a global leader in the development of innovative cannabis products and is currently distributing medical cannabis across Canada, the EU and Israel. Its research and development division, Sindica, is actively engaged in research projects relating to cultivation, product development, and pharmaceutical drug development. Aqualitas offers specialized client care services to Canadian military veterans, including VAC insurance reimbursement processing as an approved provider. We are also a producer of certified organic cannabis flower, concentrates, oils and edibles. Their products reviews by medical patients in general and veterans in particular are among the best in the industry. They offer veterans guaranteed inventory in our core offerings, early product releases for feedback, and customize our offerings and core branded

products to meet their needs. Their client care team has implemented customized service standards for veterans, with a particular lens for those suffering from PTSD, which includes specialized training in relation to non-violent crisis intervention, as well suicide prevention cues for enhanced referrals. They have a comprehensive veterans care program and are the exclusive cannabis product supply partner, and distributor of Veterans for Healing branded products. Veterans for Healing is a Nova Scotia bases social enterprise with a global reach, founded by veterans for veterans it is dedicated to providing military veterans with alternative care products and services to assist in the healing journey from traumatic injury.

The Aqualitas distribution network for veterans is national in Canada and includes their internal platform, and third party distribution through Medical Cannabis by Shoppers Drug Mart. Aqualitas is only 1 of 2 Atlantic based producers providing local support to veterans. Atlantic Canadian veterans make up approximately 44% of the programs reimbursements from approximately 16,000 veterans in total. Aqualitas is guided by a patient medical advisory board consisting of healthcare providers, patients, and patient advocates which include veterans. Aqualitas is recognized for its expertise related to working with veterans, and was invited by the Canadian Senate to make submissions regarding Canadian Veteran Use of Cannabis for Medical Purposes.

Objective 6: Provide the Grant Administrator with a grant budget to which monitoring and reporting will be tied.

MAPS financial and accounting team will provide the Grant Administrator the financial reporting required and in their preferred format. Reporting will be conducted on a modified cash basis. MAPS will provide the backup detail to justify grant funds expenditure as required by the RFP. Vendor lists will be maintained within the accounting system and will enable vendor and site-specific reporting within the unique class code assigned to the trial. MAPS performs an annual external financial audit. As MAPS does not currently meet the financial threshold of Federal funding necessary to perform a Single Audit as required by OMB Circular 200.36 (A-133 Audit), if the grant is awarded, MAPS will update auditing plans to allow for a Single Audit. Documentation to support administrative cost sharing will be retained. Company information systems are allocated at 10% to the grant, based on the number of concurrent projects funded by MAPS.

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

The sponsor intends to continue to pursue U.S. FDA approval for prescription use of inhaled botanical cannabis for treatment of PTSD and will work with MAPS PBC Executive Management, finance and accounting teams to ensure the study is initiated, executed, monitored, and controlled. Together, these teams will exercise financial and management oversight. MAPS PBC Key Personnel will be responsible for overseeing quality and accuracy of grant deliverables, working closely with investigators funded by this grant, if awarded.

Objective 8: Publish the results of the clinical trial

MAPS has published the first and only RCT on treatment of PTSD with smoked cannabis and has a track record of success (Bonn-Miller, et al., 2021). The publication plan for this study will be managed by the MAPS PBC Key Personnel to ensure timely dissemination of study data. The sponsor and investigators recognize the importance of communicating medical research and scientific data. MAPS PBC and the CRO will work in close collaboration with the investigators to implement the study, acquire, analyze, interpret data, and describe the results in line with requirements of top-tier peer-reviewed scientific journals and presentation of results at national scientific meetings. Unless otherwise required by law, all intellectual property developed using funds from this Agreement, including copyright, patent, trademark and trade secret, will belong to the Grantee. MAPS will not seek to copyright, patent, trademark or create trade secrets and will make all the data public in accordance with Open Science Principles. The publication policy and budget will be included in each subcontract. In line with requirements for publishing, this study is powered to detect small differences between groups and includes the appropriate study design and statistical analysis methods to support this plan. All publications will follow the ICMJE (International Community of Medical Journal Editors) Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals, unless other guidelines are required by the journal. Due regard shall be given to both investigators

and MAPS' mutual legitimate interests, e.g., manuscript authorship, journal selection, and coordinating with other ongoing studies in the same field. All authors will have access to the statistical reports and tables and will be expected to provide substantial intellectual and scientific contributions to the manuscript.

END APPLICANT RESPONSE

V-F 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:

(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.

(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.

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

BEGIN APPLICANT RESPONSE

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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.

   MAPS is the organizational entity sponsoring this study and is a 501(c)3 non-profit research and educational organization. MAPS currently has an open IND for botanical cannabis for treatment of PTSD with the FDA. MAPS has been an international pharmaceutical sponsor since 1985, with experience in oversight of preclinical, Phase 1 safety studies with MDMA and Phase 2-3 clinical trials of MDMA-assisted therapy for PTSD, social anxiety, and anxiety associated with life-threatening illnesses. MAPS has delegated the primary responsibility of trial organization to its sub-recipient and wholly owned subsidiary the MAPS PBC, including designing, initiating, managing, coordinating, continuing, and concluding the clinical trials within the Cannabis Clinical Development Program. Collectively, MAPS and MAPS PBC satisfy sponsor responsibilities for regulatory agencies. MAPS PBC has experience overseeing studies conducted by investigators in institutional settings since 2014 and ran the first and only Phase 2a randomized, placebo-controlled clinical trial of smoked botanical cannabis for treatment of PTSD in veterans that was referenced in this RFP (Bonn-Miller et al., 2021). Key Personnel from MAPS PBC ensured that this FDA-regulated clinical trial was conducted to the highest standards applicable to clinical research studies within the Cannabis Clinical Development Program. This sponsored study successfully passed all DEA inspections. Furthermore, this study was funded by a state government Marijuana Research Grant from the Colorado Department of Public Health and Environment (CDPHE) and Key Personnel from MAPS PBC ensured that grant deliverables were completed on time and with high quality, resulting in a Standard rating from the funding agency. The original CMS Contract Number is 16 FHHA 88230. The evaluation date was September 8, 2020 and evaluation period was between April 19, 2016 and September 1, 2020. Documentation for this project result is available upon request.

This level of study oversight is necessary because 1) PTSD is a complex and serious disorder that is associated with high levels of psychiatric and medical comorbidity & suicide risk and 2) Cannabis is a Schedule 1 controlled substance. These factors frequently present challenges that affect the success and interpretability of PTSD studies. MAPS PBC has developed an FDA and IRB-approved safety plan for responding on a 24-hour basis to any psychological crisis involving suicidal ideation or behavior, with management of participants who experience sequelae and appropriate referral in consultation with the Site PI and medical site staff.

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.

MAPS has not received a grant from the State of Michigan. (N/A)

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

For current funding sources and the level of funding for the current year and the previous ten years please see below.

Multidisciplinary Association for Psychedelic Studies 2:04 PM
10 Year Revenue by Source 07/12/2021
June 2012 through May 2021 Accrual Basis

	Jun '12 - May 21
Ordinary Income/Expense	
Income	
41100 · Products Sales	829,729
41600 · Event & Conference Income	2,915,541
41800 · Commission Income	112,541
41000 · Earned Income - Other	1,102,309
40100 · Corporate Contributions	5,533,100
40200 · Foundation Contributions	27,534,793
40300 · Individual Contributions	58,801,364
40500 · Donated Goods	142,836
40600 · Bequests	2,174,112
45000 · Investment Income	1,884,561
46000 · Government Grants	1,837,054
42000 · Fiscal Sponsorship Income	4,909,409
Total Income	107,777,349

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END APPLICANT RESPONSE

V-G 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

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Recipient and Sponsor (MAPS) Key Personnel

The following MAPS Key Personnel will ensure that grant funds are utilized within stated parameters of this grant opportunity:

Rick Doblin, Ph.D., Executive Director of MAPS: Dr. Doblin is the founder and executive director of the Multidisciplinary Association for Psychedelic Studies (MAPS). He received his doctorate in Public Policy from Harvard's Kennedy School of Government, where he wrote his dissertation on the regulation of the medical uses of psychedelics and marijuana and his Master's thesis on a survey of oncologists about smoked marijuana vs. the oral THC pill in nausea control for cancer patients. His undergraduate thesis at New College of Florida was a 25-year follow-up to the classic Good Friday Experiment, which evaluated the potential of psychedelic drugs to catalyze religious experiences. He also conducted a thirty-four year follow-up study to Timothy Leary's Concord Prison Experiment. Rick studied with Dr. Stanislav Grof and was among the first to be certified as a Holotropic Breathwork practitioner. His professional goal is to help develop legal contexts for the beneficial uses of psychedelics and marijuana, primarily as prescription medicines but also for personal growth for otherwise healthy people, and eventually to become a legally licensed psychedelic therapist. Since he founded MAPS in 1986, Dr. Doblin has worked tirelessly to fulfill the mission of MAPS, which is to study the risks and benefits of pyschedelics and cannabis and enable access to patients who need it. Of all the pathways available, Dr. Doblin has demonstrated the success of following the FDA regulatory process through fundraising and sponsoring research. Dr. Doblin will assure the appropriate use of funds from this grant, if awarded. As administrative staff are included within the indirect cost allocation, Dr. Doblin's support is not listed under direct Personnel costs.

Jami Murphy, Financial Controller of MAPS: Jami is an experienced nonprofit financial executive with a passion for helping mission-driven organizations. She has an M.B.A. with a concentration in management and strategy as well as a B.S. in accounting from Western Governors University. Additionally, Jami possesses a certificate in servant leadership from Cornell University. Professional development is important to Jami. She is a certified fraud examiner and a certified administrator of school finance and operations. Jami was drawn to the MAPS mission for helping people who suffer from PTSD. As a military veteran and the relative of first responders, she has witnessed how painful and limiting PTSD can be to those close to her. Jami will ensure that financial controls are enforced to enable veterans with PTSD to potentially benefit from the results generated by this grant. As administrative staff are included within the indirect cost allocation, Jami's support is not listed under direct Personnel costs.

Subrecipient and Sponsor Delegate (MAPS PBC) Key Personnel

The following MAPS PBC Key Personnel will ensure that open employee positions that will be funded by this grant will be fulfilled with qualified candidates that can accomplish the stated goals of this study:

Corine de Boer, M.D., Ph.D., Chief Medical Officer: Dr. de Boer received her medical degree from Radboud University in Nijmegen, the Netherlands and completed residency and fellowship training in pediatrics and pediatric nephrology. Her Ph.D. was focused on peritoneal dialysis in children, and she joined the academic staff at the Radboud University after completing her training. Before moving to the United States in 2000, she worked as a Pediatrician in the largest inner-city hospital (OLVG) in Amsterdam where she was responsible for in- and outpatient care in a multi-racial patient group including sickle-cell disease, thalassemia, and AIDS. For the last 20 years, she has contributed to the development of meningococcal and hepatitis vaccines during her tenure at GSK vaccines (formerly Novartis Vaccines and Chiron Corporation) and Dynavax prior to starting her own consulting company where she provides strategic advice and support for a variety of clients working on biologics, small molecule/polymer therapeutics and vaccines. As a part of Executive Management of MAPS PBC, Dr. de Boer will oversee the Clinical Development personnel that will be hired for this grant that will work directly with the selected Contract Research Organization, including the Medical Monitor and Clinical Program Manager to ensure all clinical operations and safety oversight are conducted according to industry best practice standards. As administrative staff are included within the indirect cost allocation, Dr. de Boer's support is not listed under direct Personnel costs.

Berra Yazar-Klosinski, Ph.D., Chief Scientific Officer: Dr. Yazar-Klosinski is responsible for development of strategic, catalytic, and capacity-building activities to facilitate research on the risk/benefit profile of psychedelics in compliance with the global regulatory landscape. She has been actively involved in the various stages of nonclinical and clinical development of MDMA-assisted psychotherapy, LSD-assisted psychotherapy, cannabis, and ibogaine. After gaining experience in clinical research laboratories with Geron Corporation and Millennium Pharmaceuticals, Dr. Yazar-Klosinski joined MAPS in 2009 to work with an organization where profit wouldn't dictate the agenda of scientific research. Over the last 10 years, she has supported MAPS clinical research and regulatory affairs through all stages of growth. Dr. Yazar-Klosinski has developed a strong track record of success with FDA, state regulatory agencies and multiple regulatory agencies outside of the USA. Dr. Yazar-Klosinski earned her B.S. in Biology with a minor in Drama from Stanford University and her Ph.D. in Molecular, Cell, and Developmental Biology from the University of California, Santa Cruz. As a part of Executive Management of MAPS PBC, Dr. Yazar-Klosinski will ensure that the scientific and regulatory strategy for the Cannabis Clinical Development Program is best positioned to facilitate U.S. FDA regulatory approval for treatment of PTSD and that the necessary MAPS PBC staff and resources are dedicated to the trial. As administrative staff are included within the indirect cost allocation, Dr. Yazar-Klosinski's support is not listed under direct Personnel costs.

Jay Nair, Ph.D., P.M.P., **Senior Director and Head of CMC:** Dr. Nair has over 30 years of expertise in chemistry, manufacturing, and controls (CMC) executive management in the pharmaceutical and biopharmaceutical industries. Over his career, he has worked at companies such as Bristol Myers Squibb (BMS), Baxter, Teva, and Cephalon. Since his position as Executive Director at BMS, he has been a management consultant in the areas of CMC, Regulatory and Project Management. He also consulted for private equity companies as a global due diligence expert, analyzing the FDA exposure and assessing the risk of target companies and their therapeutic assets. His clients included Pfizer, McKinsey & Co., Accenture, Capital Group of companies. Dr. Nair obtained his Ph.D. in Pharmaceutical Analysis from Boston University. He is a graduate of Indian Institute of Technology (IIT) Kanpur. Dr. Nair is also a certified Project Management Professional (PMP). Dr. Nair will oversee the CMC personnel that will be hired for this grant that will work directly with the selected CRO, including the Senior Manager of CMC. As administrative staff are included within the indirect cost allocation, Dr. Nair's support is not listed under direct Personnel costs.

Scott Hamilton, Ph.D. Director of Biostatistics: Dr. Hamilton has worked with MAPS since 2015 and recently joined MAPS PBC full-time. He has been deeply involved in the analysis of the Phase 2-3 studies of MDMA-assisted therapy and cannabis for PTSD. He designed the statistical aspects of the current pivotal studies. He was formerly President and Founder of DynaRand, LLC, a software company that pioneered the development of IVRS and IWRS solutions for clinical trials management. DynaRand was acquired by United BioSource Corporation in 2005. Since the inception of DynaRand in 1998, he has

pioneered the use of IXRS for automated adaptive studies, especially in the area of dynamic randomization. Dr. Hamilton has an Adjunct Professor appointment at Stanford University's School of Medicine in the Department of Neurology and Neurological Sciences, where he has been the primary statistician on multiple acute stroke studies. Dr. Hamilton sits on several data safety monitoring committees and works closely with pharmaceutical companies regarding the statistical aspects of adaptive trials and randomization algorithms. Previously, Dr. Hamilton was a statistical reviewer for the NI-NINDS Grant Review Committee. Widely published, he holds memberships in the American Statistical Association and the American Stroke Association. Dr. Hamilton received his undergraduate degree from the University of California at Davis, his Master of Science from the University of California at Los Angeles in Biostatistics, and his Ph.D. in Biostatistics from the University of North Carolina. Dr. Hamilton will develop the Statistical Analysis Plan and randomization procedures for the present study and work directly with the selected CRO that will be supporting this trial to ensure all statistical analyses are conducted and the final statistical package follows the highest quality regulatory and scientific standards.

Michelle Pleshe, Director of Data Management & Services: Michelle Pleshe earned a bachelor's degree in computer science in 1985 from Old Dominion University. Prior to joining MAPS PBC, Michelle worked in clinical data management at IQVIA, a global full-service Contract Research Organization, as Director of Programming Shared Service where she led a team of clinical study designers and validation leads. During Michelle's 29 years at IQVIA, she has worked across all phases of studies and multiple therapeutic areas. She has extensive experience in building and validating clinical studies in multiple EDC platforms and developing strong technical teams. At MAPS PBC, Michelle focuses on the oversight of clinical system and software development through the lifecycle including evaluation, implementation/development, maintenance, archiving, and documentation. Michelle joined MAPS PBC in order to use her many years of experience in clinical research to have a closer connection to the research and patients involved. She will oversee the Data Management & Services personnel that will be hired for this grant that will design, configure, validate, maintain, and close the clinical trial database and data collection systems for this trial, including the Clinical Data Manager and Dr. Julie Wang, Senior Clinical Data Scientist.

Julie Wang, M.P.H., Ph.D. Senior Clinical Data Scientist: Dr. Wang is a data scientist with clinical research expertise in public health interventions. Her dissertation and research fellowship focused on developing and testing IoT solutions in both clinical and real-world settings to promote, measure, and analyze lifestyle behaviors (i.e., diet, physical activity, and smoking cessation). Dr. Wang completed further training in data science at General Assembly in San Francisco to advance analytic skillsets in working with large and complex mobile/digital datasets. She is enthused by data-driven decision-making and psychedelic-assisted psychotherapy. At MAPS PBC, Dr. Wang supports statistical analysis of clinical data for research development and regulatory affairs. Dr. Wang holds a B.A. in Liberal Arts/ Peace Studies and Conflict Resolution and MPH (Global Health Promotion) at the George Washington University in Washington, D.C., a Ph.D. in Public Health (Behavioral Science) at UC San Diego in La Jolla, CA and completed post-doctoral research fellowship at UC San Francisco in San Francisco, CA. Dr. Wang will contribute to the biometrics integration and mobile device digital data collection start-up and machine learning exploratory analyses that are incorporated into the trial to leverage data on objective measures of sleep stages and heart rate variability which are critical variables for studying the mechanism of action of cannabis for treatment of PTSD.

Sarah Kleiman, Ph.D. Senior Independent Rater Supervisor: Dr. Kleiman is a Licensed Clinical Psychologist who specializes in the assessment and treatment of PTSD. After graduating from the Clinical Psychology PhD program at George Mason University 2014, she completed a 2-year Postdoctoral Fellowship, followed by 2 years as a Research Psychologist, at the Boston VA Medical Center where she was involved in numerous longitudinal and PTSD treatment studies being conducted through the National Center for PTSD. For the past 6 years, Dr. Kleiman has been a Research Consultant on PTSD studies conducted by non-profit organizations, pharmaceutical companies, university research groups, and VA hospitals. Her area of expertise is in providing training, supervision, and data integrity oversight of psychodiagnostic measures, especially the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). Dr. Kleiman has provided supervision of the CAPS-5 and other instruments in her role as Senior Independent Rater and Clinical Investigator of the Independent Raters for studies, including MDMA and cannabis studies for treatment of

PTSD, sponsored by MAPS for the past 5 years. In addition, Dr. Kleiman has been an undergraduate Course Instructor at Harvard University, and undergraduate and graduate Course Instructor and Thesis Director at Harvard Extension School, for 12 semesters. Dr. Kleiman will oversee the Independent Rater Pool responsible for generating primary and key secondary outcomes from the trial and will work directly with the Independent Rater Program Manager that will be hired to support this trial.

Subcontracted Contract Research Organization:

Contract Research Organizations (CROs) enable healthcare transformation by providing advisory support to research sponsors to uncover opportunity, accelerate innovation, and improve outcomes for patients around the world. The chosen CRO will work closely with MAPS PBC to bring to cannabis to market as a prescription medicine through the U.S. FDA. CRO practice areas include study management and implementation, site monitoring and monitoring management, safety/pharmacovigilance, clinical data collection forms and tools, biostatistics and statistical programming, medical writing, and pass-through costs for site start-up/activation, IRB review, and monitoring travel. The competitive bidding process for this function resulted in four companies declining to bid and two full proposals. The proposals will be reviewed by MAPS PBC and fine-tuned within the cost allocation specified in the budget for this grant application, while retaining optimal quality for subcontracted services.

Subcontracted Risk Mitigation Services:

WCG Analgesic Solutions, Inc. has provided a sole source proposal to reduce measurement error and mitigate the magnitude of the placebo response that was observed in the first RCT to better position the second RCT of cannabis for treatment of PTSD for success. These tools include Placebo Response Reduction Training (PRR) and Accurate Symptom Reporting Training (ASR). WCG Analgesic Solutions, LLC., was founded in 2006 and acquired by the WIRB-Copernicus Group (WCG) in 2019, a privately held company focused on increasing assay sensitivity with a focus on pain clinical trials through consulting, innovative tools and technology, and training. Nathaniel Katz M.D., M.S. is an expert who helps clients develop and commercialize better treatments for pain. With hundreds of projects completed and ongoing collaborations with regulatory authorities, WCG AS is the leader at identifying and mitigating the random and systematic errors that lead to failed clinical trials. WCG AS will take a hands-on, systematic approach toward the implementation of the PTSD de-risking package to ensure that staff and subject behaviors are modified appropriately. A WCG AS Project Manager will be assigned to the program to serve as the primary point of contact to MAPS for the delivery and implementation of the training. Services will include live training at the Investigator Meeting with role plays. A WCG AS trainer will lead study staff in PRR Training and ASR Training. Clinical trial staff and veterans enrolled in the study will have access to an Online Learning Management System, which will be used to host all training materials, certificates and completion reports, and user guides for clinical trial site staff. The ASR training program has been used effectively in more than 80 unique trials, 15 indications, across 39 different countries, with over 70,000 subjects trained to date. The WCG AS Training program (and no other) has been validated through multiple lines of research.

Subcontracted Clinical Trial Site Key Personnel:

Site 1 – Veterans Administration Ann Arbor Health System (VAAAHS) in Ann Arbor, Michigan

Maria Silveira, M.D., M.A., MPH, Principal Investigator: Dr. Silveira is a Research Scientist at the Ann Arbor VAMC Geriatric Research Education and Clinical Center (GRECC) and an Associate Professor in Internal Medicine (Geriatric and Palliative Medicine) at the University of Michigan. She is a graduate of Harvard College and SUNY Stony Brook School of Medicine and completed her residency in Internal Medicine at Oregon Health Sciences University. She has two Master's Degrees, one in Health Services from the University of Washington and another in Medical Ethics from the University of Pittsburgh. Her 20 years of clinical work with Veterans and their families inspires her clinical research in symptom management. She received a VA Merit award to conduct a successful trial of web-based caregiver

support for symptom management among cancer patients receiving chemotherapy. She is site-PI on a PCORI-funded comparative effectiveness study into tele-palliative care. These studies have given her experience in recruiting patients, gathering data, and analyzing data for clinical trials. Dr. Silveira's time is equally divided between the Ann Arbor VAMC and the University of Michigan; her time on this study will come from her UM portion. There is a Memorandum of Understanding to this effect. Her interest in the topic of this proposal was inspired by her clinical observation that among the hundreds of veterans whom she has treated for cancer pain over the years, many have poorly treated PTSD and benefit from marijuana. She believes a trial such as the one proposed will be of utmost importance to her patients.

Site 2 – Functional Pain & Rehabilitation Service in Detroit, Michigan

Annas Aljassem, M.D., MHSA, Principal Investigator: Dr. Aljassem is Board Certified in Physical Medicine & Rehabilitation, Hospice and Palliative Medicine, Pain Medicine, Traumatic Brain Injury and Addiction Medicine. Dr. Aljassem has served as the Co-Investigator for past FDA-regulated clinical trials at the Functional Pain & Rehabilitation Service clinic, most recently involving COVID-19 through an investigator initiated study of immunomodulation to treat COVID-19 using low-dose Naltrexone and Ketamine infusions (ClinicalTrials.Gov ID - NCT04365985: Study of Immunomodulation Using Naltrexone and Ketamine for COVID-19 (SINK COVID-19). The clinic is well equipped and understands the complexity and intricacies of working with grant funds. Dr. Aljassem designed, hired and implemented a grant to create the Beaumont Addiction Medicine service. The grant focused on Medication Assisted Treatment (MAT) awarded for a total of $1M from the Community foundation Southeast Michigan in 2019. Funding was used for the development and implementation of a self-sustaining Opioid Use Disorder program at Beaumont Health based on gap analysis based on medical provider input. The funding established initial services for referral and initiation of MAT while patients were admitted to the inpatient hospital and for a dedicated medical social worker to help identify, coordinate existing addiction medicine resources within the patient's community, and provide a warm hand off to an outside facility/provider. The staff also dedicated time to help to prevent medication misuse and reduce harm through education of prescribers and the public. As a senior PM&R resident, Dr. Aljassem worked with veteran patients at the Detroit VA under Dr. Michael Stellini, the Chair of the palliative care program. Dr. Aljassem also completed a fellowship in Hospice & Palliative Medicine at the University of Michigan in 2015 in both the inpatient and outpatient settings at the Veterans Hospital in Ann Arbor. Utilizing his ties to both the Detroit VA and Ann Arbor VA, Dr. Aljassem will oversee the recruitment, treatment, safety management and data collection of 60 participants in this clinical trial in his role as the Site Principal Investigator of this RCT.

Site 3 – James A. Haley VAMC in Tampa, Florida

Mark S. Kindy, PhD, Principal Investigator: Dr. Kindy is a Senior Research Career Scientist from James A. Haley VAMC will serve as the Principal Investigator of the subcontract with the Haley VAMC and has had experience with various clinical trials over the years. Dr. Kindy has participated in various clinical programs and trials over his career at the University of Kentucky (Lexington VA), Medical University of South Carolina (Ralph H. Johnson VAMC) and now at the University of South Florida (James A. Haley VAMC, 2015). He has served as PI/Co-PI on various projects, contributing to recruitment of patients, collection of materials, analysis of samples, and data.

Praveen Gootam, M.D., Co-Investigator: Dr. Gootam has been affiliated with the Haley VAMC for the last 15 years and has participated in a number of clinical research studies and trials over the last few years. He is a psychiatrist with expertise in PTSD and other neurological disorders.

Fabio Leonelli, M.D., Sub-Investigator: Dr. Leonelli is a clinical Electrophysiologist with over 25 years experience in the management of a large variety of arrhythmias but a specific interest in Atrial Fibrillation. Together with his clinical practice he has maintained a profound interest in the academic side of medicine authoring well over 150 between papers and abstracts dealing with modeling of fibrillation to modern procedures and has been the recipient of numerous Grants. The directorship of cardiac clinical research at one of the largest VA in the country has allowed Dr. Leonelli to create a

research group well versed in data mining as well as very knowledgeable in the recruitment of patients for clinical studies and able to use modern technologies to connect the protected VA environment with the outside world. Dr. Leonelli will help with the clinical trial especially with the EKGs and recruitment as he runs the Clinical Research Center at the VA.

Site 4 – Scottsdale Research Institute in Phoenix, Arizona

Suzanne Sisley, M.D., Principal Investigator: Dr. Sisley has degrees from Arizona University (B.S.), and the University of Arizona, Tucson (M.D.). She completed post-doctoral residencies in internal medicine and psychiatry at Good Samaritan Regional Medical Center in Phoenix, AZ. She is an experienced board-certified adult psychiatrist with expertise in telemedicine. For three years, she worked with PTSD patients as a psychiatrist at the Phoenix VA. For over 14 years, she has provided psychiatric evaluation and medication monitoring via telemedicine and developed novel applications of telemedicine at the Arizona Telemedicine Program and as Director of Telemedicine at the Scottsdale Treatment Center. For the past nine years, she has served at the University of Arizona College of Medicine as attending physician for a large outpatient adult psychiatry clinic with over 1,200 cases a year. She provided direct supervision of adult crisis cases in psychiatric emergency rooms and urgent care centers across Arizona. For three years, Dr. Sisley served as Sub-I in a series of Phase 3 and 4 clinical trials conducted at Pivotal Research Centers performed on novel psychoactive drugs examining the range of physiological and psychological effects of administering study drugs on adults. Dr. Sisley has invested the last four years in obtaining approval and funding for the proposed study and is fully committed to seeing this study through completion in service of the 600,000 veterans in Arizona through her connections with Veteran Service Organizations. Dr. Sisley holds federal DEA Schedule 1 Researcher and Manufacturer licenses for cannabis. As the Principal Investigator of the first RCT of cannabis for treatment of PTSD, Dr. Sisley is uniquely qualified with hands-on experience in conducting clinical trials of cannabis for treatment of PTSD in a veteran population. Dr. Sisley will oversee the recruitment, treatment, safety management and data collection of 60 participants in this clinical trial in her role as the Site Principal Investigator of this RCT.

Sites 5,6 – TBD in Michigan

Two additional clinical trial sites will be added to this study with appropriately qualified key personnel who have demonstrated the ability to recruit veterans within the state of Michigan.

Detailed organization charts of MAPS and MAPS PBC:

Please see attached for a detailed organizational chart of MAPS and MAPS PBC including names, titles, of all individuals that will contribute to the project. As both companies are fully distributed and employees work from home, geographic location is not applicable to their work and hence not provided.

Confidentiality Agreement Signatures and Dates:

Please see attached for a copy of our confidentiality agreement and the list of personnel and the date that the confidentiality agreement was signed.

Rick Doblin	July 16, 2021
Drew House	July 16, 2021
Jami Murphy	July 16, 2021
Corine de Boer	July 15, 2021
Rebecca Matthews	July 15, 2021
Berra Yazar-Klosinski	July 15, 2021
Jay Nair	July 15, 2021
Michelle Pleshe	July 15, 2021

Scott Hamilton	July 16, 2021
Julie Wang	July 15, 2021
Julie Blaisdell	July 15, 2021
Mo Septimus	July 16, 2021
Ryan Hudgins	July 15, 2021
Mike Ruggles	July 15, 2021
Jane Zahniser	July 15, 2021
Judy Calkins	July 15, 2021
Desra Diehl	July 15, 2021
Erica Scott	July 15, 2021
Jamelia Avalos	July 16, 2021
Larry Narachi	July 15, 2021
Andrew Marty	July 15, 2021

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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 grant related. 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 as possible.

- **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.

BEGIN APPLICANT RESPONSE

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Budget Narrative

The applicant for this grant is the non-profit MAPS, with support from its wholly owned subsidiary and subrecipient MAPS PBC. The budget provided in Attachment A does not include matching, leveraged, cost share or any other type of supplemental funds. The applicant has negotiated the majority of the costs for the lowest cost possible, unless otherwise specified below. The budget describes a sponsored clinical trial that is planned as a 36-month project, screening 1,440 potential veterans for study eligibility, and enrolling and treating 360 veterans with inhaled botanical cannabis. Both the time and the numbers of veterans are subject to change. The budget includes built in contingencies in order to account for possible delays and for study supply shortages that may arise due to the ongoing COVID-19 global health pandemic. The first 6 months of the project will include start-up activities, dedicated to preparation of personnel, supplies, information systems, and clinical trial sites and staff for VMR purposes. The clinical trial staff training will kick off with an in-person Investigator Meeting planned for January 2022. Sites will be initiated by the Contract Research Organization and opened for screening by February 2022. The Last Patient Last Visit is anticipated in December 2023 followed by database lock and data analysis for publications and the Final Clinical Study Report for the U.S. FDA in 2024.

Administrative Costs included within the 10% de minimis Indirect rate stipulated per the funding guidelines, as costs and scope for these roles exceed the scope of this specific grant, a unit cost is not provided as it exceeds the 10% indirect allocation:

Line

4, 26 Rick Doblin, MAPS Executive Director (Salary and 27% Fringe)

Will assure the appropriate use of grant funds through setting financial controls, organizational strategy, and resource allocations to the study organization-wide throughout the 36-month grant period.

5, 27 Drew House, MAPS Interim Chief Financial Officer (Salary and 27% Fringe)

Utilizing his extensive experience in administration of pre and post-award grants, will function as the Authorized negotiator for the grant, if awarded. Will assure the appropriate use of grant funds through creating and establishing methods for financial controls, planning, and carrying out activities to support external financial audit-readiness organization-wide throughout the 36-month grant period.

6, 28 Jami Murphy, MAPS Financial Controller (Salary and 27% Fringe)

Will manage accounting and monitor internal controls, oversee banking and finance activities, proper reporting and payment to all taxing authorities, insurance recommendations and related purchases and corporate documentation throughout the 36-month grant period.

7, 29 Andrew Septimus, MAPS PBC Chief Finance Officer (Salary and 27% Fringe)

Will assure the appropriate use of grant funds through creating and establishing methods for financial controls, planning, and carrying out activities to support external financial audit-readiness of MAPS PBC throughout the 36-month grant period.

8, 30 Ryan Hudgins, MAPS PBC Director of Financial Planning and Analysis (Salary and 27% Fringe)

Will lead budgeting and forecasting cycles, modeling financial and operational analytics, and developing metrics to evaluate and direct business performance to support grant-funded activities of MAPS PBC throughout the 36-month grant period.

9, 31 Mike Ruggles, MAPS PBC Financial Analyst (Salary and 27% Fringe)

Will support budgeting and forecasting cycles, modeling financial and operational analytics, and developing metrics to evaluate and direct business performance to support grant-funded activities of MAPS PBC throughout the 36-month grant period.

10, 32 Jane Zahniser, MAPS PBC Program Analyst (Salary and 27% Fringe)

Will support budgeting, forecasting, and reporting of subcontractors, including clinical trial sites, from contract & budget execution through to completion to assess performance throughout the 36-month grant period.

11, 33 Judy Calkins, MAPS PBC Financial Controller (Salary and 27% Fringe)

Will manage accounting and monitor internal controls, oversee banking and finance activities, proper reporting and payment to all taxing authorities, insurance recommendations and related purchases and corporate documentation throughout the 36-month grant period.

12, 34 Desra Diehl, MAPS PBC Staff Accountant (Salary and 27% Fringe)

Will handle bookkeeping and prepare financial documents, e.g. profit-and-loss statements and balance sheets, prepare reports, and process financial information throughout the 36-month grant period.

13, 35 Erica Scott, MAPS PBC Director of People & Culture (Salary and 27% Fringe)

Will oversee hiring and employee relations of all the departments of MAPS PBC and ensure that they are being managed according to MAPS PBC standards. Will plan, lead, and enforce recruitment, management, and employee relations policies. Given that multiple open positions within MAPS PBC are budgeted to support grant-funded activities, will fulfill a critical role in supporting this growth throughout the 36-month grant period.

14, 36 Michelle Lacy, MAPS PBC HR Senior Manager (Salary and 27% Fringe)

Will be responsible for the management of HR staff and leading the overall HR functions including work-force planning, recruitment, staff administration management, staff development and supporting MAPS PBC growth throughout the 36-month grant period.

15, 37 Jamelia Avalos, MAPS PBC HR Manager (Salary and 27% Fringe)

Will plan, coordinate, and direct the administrative HR functions of MAPS PBC, including recruiting, interviewing, and hiring of new staff and serve as a link between MAPS PBC's executive management and its employees while supporting company growth throughout the 36-month grant period.

16, 38 Christopher White, MAPS PBC Director of IT (Salary and 27% Fringe)

Will be responsible for the management, strategy and execution of IT infrastructure of MAPS and MAPS PBC. Will oversee technical projects in alignment with organizational goals. Will direct the effective delivery of networks, development, data privacy, and disaster recovery systems and processes, following and enforcing the Data Security Plan throughout the 36-month grant period.

17, 39 Larry Narachi, MAPS PBC IT Manager (Salary and 27% Fringe)

Will plan, direct and oversee activities dealing with MAPS and MAPS PBC computer and information systems. Will coordinate the hardware, software and cloud-based network services throughout the 36-month grant period.

18, 40 Andrew Marty, MAPS PBC IT Support Technician (Salary and 27% Fringe)

Will provide assistance to MAPS and MAPS PBC computer users, resolving technical problems and maintaining cloud-based network services, software and computer equipment throughout the 36-month grant period.

19, 41 Corine de Boer, MAPS PBC Chief Medical Officer (Salary and 27% Fringe)

As a critical leader of Executive Management of MAPS PBC, the CMO is accountable to the CEO and Board of Directors of MAPS PBC for the medical governance framework and its effectiveness for all clinical trials sponsored by MAPS. The CMO provides the appropriate clinical research industry experience necessary to make medically-sound decisions, as required, to ensure patient safety and data integrity. The CMO oversees the Clinical Development Business Unit of MAPS PBC which includes the Safety and Clinical Operations Departments. The CMO will ensure qualified personnel are recruited and hired for the Medical Monitor role listed under direct VMR Program Personnel and supervise them throughout the 36-month grant period.

20, 42 Berra Yazar-Klosinski, MAPS PBC Chief Scientific Officer (Salary and 27% Fringe)

As a critical leader of Executive Management of MAPS PBC, the CSO reports to the CEO of MAPS PBC. The CSO oversees the Research & Development Business Unit of MAPS PBC which includes the CMC, Data Management & Services, and Regulatory Affairs Departments. The CSO will participate in ensuring qualified personnel are recruited and hired for the CMC Senior Manager and Clinical Data Manager roles listed under direct VMR Program Personnel, and that the design and conduct of the clinical trial will yield evaluable data suitable for U.S. FDA approval of botanical cannabis for treatment of PTSD throughout the 36-month grant period.

21, 43 Rebecca Matthews, MAPS PBC Chief Clinical Operations Officer (Salary and 27% Fringe)

As a critical leader of Executive Management of MAPS PBC, the CCOO reports to the CMO of MAPS PBC. The CCOO oversees the Clinical Operations Department of MAPS PBC and is responsible for clinical trial operations of MAPS-sponsored trials worldwide. The CCOO will ensure qualified personnel are recruited and hired for the Clinical Program Manager role listed under direct VMR Program Personnel and supervise them throughout the 36-month grant period.

22, 44 Jay Nair, MAPS PBC Senior Director and Head of CMC (Salary and 27% Fringe)

As a part of the Leadership Team of MAPS PBC, the Sr. Director and Head of CMC reports to the CSO of MAPS PBC. The Head of CMC will ensure the botanical cannabis studied in this clinical trial is produced, packaged, and processed following applicable Good Manufacturing Practices. The Head of CMC will ensure qualified personnel are recruited and hired for the Senior Manager of CMC role listed under direct VMR Program Personnel and supervise them throughout the 36-month grant period.

23,45 Allison Coker, MAPS PBC Regulatory Affairs Manager (Salary and 27% Fringe)

Will ensure that all U.S. FDA regulatory communications are efficient, accurate, and timely. Will supervise the Regulatory Operations Specialist listed under direct VMR Program Personnel throughout the 36-month grant period.

49 10% Allocation for cost of administrative information systems.

50 10% Allocation for clinical trial insurance policy premiums

VMR Program Personnel Costs:

For MAPS PBC VMR Program personnel, salary that is listed as directly contributing to the budget does not include sick pay, vacation pay, holiday pay, bonuses, overtime, tuition reimbursement/remission, vehicle allowance, seminars, conferences, meetings, subscriptions, dues, and memberships. Fringe rates are calculated as 27% of the adjusted salary costs and include health, dental, and optical insurance, employer-paid Social Security and Medicare tax, 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%).

Line

62, 73 Open Position, MAPS PBC Clinical Program Manager

90% Effort for salaried employee with 27% fringe at average monthly cost of [redacted] salary and [redacted] fringe for 36 months. Responsible for Cannabis Program and CRO Management, manages study timelines, conduct, and deliverables in line with budgets. Ensures Good Clinical Practice (GCP) requirements are followed by CRO and clinical trial sites.

63, 74 Julie Blaisdell, MAPS PBC Regulatory Operations Specialist

20% Effort for salaried employee with 27% fringe at average monthly cost of [redacted] salary and [redacted] fringe for 36 months. Responsible for regulatory submissions, adverse event reporting, annual reports, and Investigator Brochure updates for cannabis to ensure regulatory compliance.

64, 75 Scott Hamilton, MAPS PBC Director of Biostatistics

25% Effort for salaried employee with 27% fringe at average monthly cost of [redacted] salary and [redacted] fringe for 36 months. Responsible for Statistical Analysis Plan, statistical analysis, ensuring data collection meets the needs of the trial design, and randomization.

65, 76 Julie Wang, MAPS PBC Senior Clinical Data Scientist

50% Effort for salaried employee with 27% fringe at average monthly cost of [redacted] salary and [redacted] fringe for 11 months during start-up and close-out of the trial. Responsible for setting up biometrics integration with mobile device, exploratory digital data collection with the Oura Ring and machine learning analysis of sleep and heart rate variability data.

66, 77 Open Position, MAPS PBC Senior Manager CMC

50% Effort for salaried employee with 27% fringe at average monthly cost of [redacted] salary and [redacted] fringe for 36 months. Responsible for GMP cannabis supply, working with manufacturer in Canada and packaging and processor in Israel for Syqe Med Inhaler devices. Responsible for international import/export of Schedule 1 controlled substance (cannabis) according to DEA and FDA regulations and quotas, delivery to central U.S. distribution site at Scottsdale Research Institute, and subsequent distribution to clinical trial sites for dispensation to veterans per randomization procedures.

67, 78 Open Position, MAPS PBC Clinical Data Manager

33% Effort for salaried employee with 27% fringe at average monthly cost of [redacted] salary and [redacted] fringe for 36 months. Responsible for configuration, maintenance, and database lock and archival of the Electronic Data Capture system for the trial. Responsible for data review, querying, and closure as data manager.

68, 79 Michelle Pleshe, MAPS PBC Director of Data Management & Services

33% Effort for salaried employee with 27% fringe at average monthly cost of [redacted] salary and [redacted] fringe for 36 months. Responsible for oversight and management of the data management and data science personnel working on the trial. Ensures that information systems required to support the study for VMR purposes are appropriately designed, tested, validated,

deployed, maintained, locked, and archived per GxP guidelines and clinical research industry best practices.

69, 80 Open Position, MAPS PBC Independent Rater Program Manager

90% Effort for salaried employee with 27% fringe at average monthly cost of [redacted] salary and [redacted] fringe for 36 months. Responsible for oversight of bias minimization procedures that apply to critical endpoint data from the clinical trial. Coordinates Independent Rater Pool which conducts clinician-administered interviews with veterans participating in the clinical trial. Responsible for record retention, data entry and integrity.

70, 81 Open Position, MAPS PBC Medical Monitor

50% Effort for salaried doctoral-level employee with 27% fringe at average monthly cost of [redacted] salary and [redacted] fringe for 36 months. Responsible for safety oversight of the clinical trial. Ensures study is done in compliance with regulations, regulatory reporting requirements for adverse events are met, and patient safety is appropriately safeguarded.

VMR Supplies, Materials, and Equipment

Line

93 Costs of Information Systems Related to VMR Functions

10% allocation of GxP information system subscription costs at average monthly cost of $4,491 for 36 months that are utilized by MAPS PBC to support MAPS-sponsored clinical trials at the program level. This includes: randomization, SAS statistical analysis software, Electronic Data Capture system, Pharmacovigilance system, Validated Electronic Signature system, Clinical Trial Management System, Regulatory Information Management system, Quality Management System, WHO-Drug Licensing.

94 Clinical Trial Record Retention and Archival

Long term clinical trial record retention costs for 6 clinical trial sites at $175 per month per site for 300 months. Canadian regulations require that clinical trial records are retained for 25 years (300 months) after the clinical trial is completed.

95 Water Pipes for cannabis inhalation for clinical research sites

360 water pipes will be purchased at $45 per pipe plus $125 shipping per site for each of 6 sites to give veterans the option to inhale through the smoking route during the clinical trial.

96 Magazine with 8 Dosing capsules for cannabis for clinical research sites (contingency)

This cost is included as a contingency in case the inhalers are not found to be suitable for the purpose of this clinical trial. In this event, the cannabis will be loaded into dosing capsules. The magazine cartridges hold 8 dosing capsules each for the Mighty vaporizer. Cost of 400 cartridges at $15.99 per cartridge at $6,394 is included.

97 Sharps Containers for cannabis for clinical research sites (contingency)

This cost is included as a contingency in case the inhalers are not found to be suitable for the purpose of this clinical trial. In this event, the cannabis will be loaded into dosing capsules. Sharps containers will be given to participants to store the dosing capsules that have been used so they can bring them to the clinical trial site for drug accountability purposes. Cost of 400 containers at $9.99 per container at $3,996 is included.

98 Cannabis Dosing Capsules for clinical research sites (contingency)

This cost is included as a contingency in case the inhalers are not found to be suitable for the purpose of this clinical trial. In this event, the cannabis will be loaded into dosing capsules. Cost of 8000 sets of 40 dosing capsules each at $50.15 per set for $401,200 is included.

99 Mighty Vaporizer for cannabis inhalation for clinical research sites (contingency)

This cost is included as a contingency in case the inhalers are not found to be suitable for the purpose of this clinical trial. In this event, the cannabis will be loaded into dosing capsules for the Mighty Vaporizer. The cost of 360 Mighty Vaporizers at $353.33 per vaporizer for $127,200 is included.

100 Filling Set for 40 Dosing Capsules for cannabis for clinical research sites (contingency)

This cost is included as a contingency in case the inhalers are not found to be suitable for the purpose of this clinical trial. In this event, the cannabis will be loaded into dosing capsules. The filling set will enable the clinical trial sites to ensure that dosing capsules are properly closed for use in the Mighty Vaporizer. Cost of 12 filling sets at $75 per set for $900 is included.

101 Cannabis Drug cost

Purchase cost of $50,000 for 10,800g of Placebo Cannabis at $4.63 per gram. 360 veterans will be given 2 grams of botanical cannabis per day for 37 days in this clinical trial. The purchase amount includes 20% overage to account for waste during processing. The supplier is waiving the cost of 21,500g of High THC Cannabis for U.S. veterans.

102 Central Reader for Digital ECG Data

Digital ECG data retrieval, hosting and analysis fees for 24 months at $4,629.58 per month. FDA requested the addition of continuous digital ECG data to the introductory sessions on two consecutive days when veterans are first exposed to the cannabis group they are randomized to in this trial.

103 Outcome Measure Licensing Fees

The licensing fees for copyrighted clinical outcome measures are included for 1440 screened candidates at $35.24 per candidate for a total of $50,740.

104 IRB Fees

The cost of IRB submission fees are included at $12,000 per clinical trial site for 6 clinical trial sites or a total of $72,000 for the 24 month duration of the trial.

105 Study Closeout Fees
The cost of study closeout fees are included for 4 institutional clinical trial sites at $1,500 per trial site or a total of $6,000.

106 iPad Devices

$9,900 purchase cost for iPad Mini 5th generation from AT&T with bulk discount at $100 per unit plus 10% tax for 90 devices is included for hosting the Mobile app that will monitor smoking vs. vaping preferences and Changes in Health for veterans participating in the study. The iPad will also interface with the Oura Ring.

107 Oura Ring Biometric Surveillance Device

$160,000 purchase cost for 400 units at $400 per Oura Ring Biometric Surveillance Device is included to measure Heart Rate Variability and Sleep stages during the 5 week dosing period, which are important biomarkers for PTSD treatment outcomes.

108 Data Service Charges

$48,600 is included for data service charges for the iPad devices so that veterans will have access to cellular internet during the trial in order to upload the data they will generate while using their study cannabis on an outpatient basis. Service charges include $20 per device per month for 90 devices and 27 months (2430 device months).

109 Recruitment Website

To supplement recruitment efforts through VA networks and Veteran Service Organizations, the

$45,000 cost of initial build of a recruitment website and $5,000 per month hosting fee for 24 months is included.

VMR Contractual Services

The quotes for contractual services below were obtained through a competitive RFP process unless otherwise specified below. However, due to time constraints or capacity/resource constraints, the clinical trial sites and the Contract Research Organization RFP process did not proceed as originally intended. The clinical trial sites should be reviewed as potential sites and will be further assessed in detail by the sponsor and designee if the grant is awarded. The CRO services will be necessary to fully assess potential sites and researchers prior to considering them fully confirmed. Michigan firms were prioritized whenever possible. Documentation is available upon request.

Line

112 Clinical Site 1: Ann Arbor VAMC in Ann Arbor, Michigan

The Ann Arbor VAMC put together a proposal of $1,099,840 for the conduct of the trial as one of 6 clinical trial sites, treating 60 veterans with PTSD in this trial.

113 Clinical Site 2: Functional Pain & Rehabilitation Service in Detroit, Michigan

The Functional Pain & Rehabilitation Service clinic put together a proposal of $1,135,708 for the conduct of the trial as one of 6 clinical trial sites, treating 60 veterans with PTSD in this trial.

114 Clinical Site 3: James A. Haley VAMC in Tampa, Florida

The PI from James A. Haley VAMC put together a proposal of $760,885 for the conduct of the trial as one of 6 clinical trial sites, treating 60 veterans with PTSD in this trial.

115 Clinical Site 4: Scottsdale Research Institute in Phoenix, AZ

The Scottsdale Research Institute put together a proposal of $1,589,500 for the conduct of the trial as one of 6 clinical trial sites, treating 60 veterans with PTSD in this trial.

116 Clinical Site 5: TBD, Michigan (with contingency)

The sponsor intends to pursue solicitation of two additional clinical trial sites in Michigan if the grant is awarded and representative costs based on the other sites have been included with contingencies.

117 Clinical Site 6: TBD, Michigan (with contingency)

The sponsor intends to pursue solicitation of two additional clinical trial sites in Michigan if the grant is awarded and representative costs based on the other sites have been included with contingencies.

118 Contract Research Organization

The Contract Research Organization RFP was sent to six candidate firms who all indicated initial interest in applying. However, four firms subsequently declined very close in time to the due date, resulting in only 2 proposals being obtained in time. In addition, proposals that were received should be appropriately evaluated and fine-tuned prior to being considered final by MAPS PBC Key Personnel. If the grant is awarded, we intend to complete this evaluation process and stay within the cost of $3,194,762 that has been budgeted for this line item.

119 GMP Cannabis Packaging and Processing of Syqe Inhaler

The GMP Cannabis Packaging and Processing RFP was sent to three candidate firms. One firm declined, due to concerns of possible contamination of their GMP equipment by pesticides. It should be noted that the cannabis source information was not shared with the candidate firm so there was no verifiable basis for this concern. A second firm quoted a very high number due to the need to purchase primary equipment in order to do the work. The budgeted proposal of $360,000 is the most reasonable proposal from Syqe Med but does involve shipping the study

cannabis from Canada to Israel to the GMP facility, and subsequently importing into the U.S. for distribution to clinical trial sites.

120 WCG Analgesic Solutions, Inc. – Placebo Response Reduction Training

WCG Analgesic Solutions is a sole source contractor for Placebo Response Reduction Training. As such, it was not possible to conduct a competitive bidding process for this service. The original proposal was negotiated as much as possible down to $280,820 to best utilize the proposed grant funds. As a sizeable placebo response was dedicated from the first RCT of cannabis for treatment of PTSD, this expense appears to be necessary.

121 Quantified Citizen - Mobile Application

The mobile application service to be hosted on the study iPad devices was selected through a competitive bidding process. Three bids were obtained. Of these bids, one was very high. The remaining two were comparable on monthly services of $1,800 per month for 24 months and setup costs. However, Quantified Citizen had the added features of providing mobile device management services and biometrics integration and although this was an added cost, it was found to be more feasible and cost effective than paying in-house personnel to do this work. As such, the Quantified Citizen proposal was selected for a total of $79,700.

VMR Travel (VMR Staff)

Line

124 Investigator Meeting Transportation

Out of state airfare of $1000 per person for 9 VMR Program Staff, and in-state transportation for 4 VMR staff per site for 6 clinical trial sites at $1000 per person is budgeted for this meeting.

125 Investigator Meeting Meals

The cost of 1 lunch at $25 per lunch and 3 dinners at $50 per dinner is included for 33 VMR Staff for a total of $5,775.

126 Investigator Meeting Lodging

The cost of a hotel is included for 33 people at $150 per night for 3 nights (99 people nights), for a total of $14,850.

127 Investigator Meeting Venue

The cost of the venue and included lunches for VMR Program Staff is budgeted for $20,000 per day for 2 days of meetings with capacity of up to 60 attendees, including personnel from the Contract Research Organization, WCG Analgesic Solutions, and Syqe Med whose travel won't be covered. A venue in the state of Michigan will be selected.

VMR Other Costs

Line

130 Independent Rater Pool

The cost of clinician-administered screening, baseline and endpoint assessments are included for 1440 screened participants at $520 per participant for a total of $748,800 per assessment by the Independent Rater Pool.

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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.

BEGIN APPLICANT RESPONSE

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TAMPA VA
Research and Education Foundation, Inc.
www.tampavaref.org
5620 E. Fowler Ave., Suite B, Temple Terrace, FL. 33617-2373 | Phone: (813) 780-2623 | Fax: (813) 779-8652

July 14, 2021

Rick Doblin, Ph.D.
Multidisciplinary Association for Psychedelic Studies (MAPS)
3141 Stevens Creek Blvd #40563
San Jose, CA 95117

Dear Dr. Doblin:

It is my pleasure to provide this letter of support to MAPS for the proposal entitled "Phase 2 Multicenter Randomized Placebo-controlled, Double-blind, Parallel Study to Assess the Safety and Efficacy of Inhaled Cannabis in Veterans for Treatment of Posttraumatic Stress Disorder (PTSD)". Dr. Mark Kindy will serve as the Tampa site PI for the proposal, along with Drs. Praveen Gootam and Fabio Leonelli.

All three researchers have extensive experience in clinical trials and the conduct of clinical research. The James A. Haley Veterans' Hospital (JAHVH) has a very large population of veterans with acute and chronic PTSD so a study of this magnitude would benefit them tremendously. Studies of this nature will also help to define the efficacy of cannabis and cannabis derivatives on other veteran related disorders including neuropathic pain, TBI, etc.

The Foundation is a congressionally created non-profit corporation 501(c)(3) for the purpose of providing administrative support of non-VA funded research projects. As such, we abide by all laws and policies established for the VA. The Foundation will provide administrative, procurement, accounting, and fiduciary reporting within federal guidelines.

We look forward to a successful application and the subsequent clinical trial on cannabis and PTSD. Please contact me if you have any questions.

Sincerely,

Douglas Reeder

Douglas Reeder, MBA, CNPM
Executive Director
Tampa VA Research and Education Foundation

DEPARTMENT OF VETERANS AFFAIRS
James A. Haley VA Medical Center
13000 Bruce B. Downs Blvd
Tampa, Florida 33612

Rick Doblin, Ph.D.
Multidisciplinary Association for Psychedelic Studies (MAPS)
3141 Stevens Creek Blvd #40563
San Jose, CA 95117

Dear Dr. Doblin,

It is my pleasure to provide this letter of support to MAPS for the proposal entitled "Phase 2 Multicenter Randomized Placebo-controlled, Double-blind, Parallel Study to Assess the Safety and Efficacy of Inhaled Cannabis in Veterans for Treatment of Posttraumatic Stress Disorder (PTSD)". As we discussed, the James A. Haley VA Medical Center is excited to partake in the application and the clinical trial. I will be serving as the PI of the subcontract with the Haley VA, and have had experience with various clinical trials over the years. In addition, Dr. Praveen Gootam will serve as the Co-PI and Dr. Fabio Leonelli will help with the clinical trial especially with the EKGs and recruitment as he runs the Clinical Research Center at the VA. The Haley VA is one of the largest VA in the network and sees over 12,000 Veterans with PTSD on an annual basis. Many of these Veterans are willing to participate in clinical trials to help alleviate the various ailments that afflict them.

I look forward to a submission of the application and the funding of the clinical trial on cannabis and PTSD. Please let me know if you have any questions.

Sincerely,

Mark S. Kindy, Ph.D.
Senior Research Career Scientist
James A. Haley VAMC
Tampa, FL
813-974-1468
Mark.kindy@va.gov
kindym@usf.edu

Veterans Alliance for Holistic Alternatives

6/28/2021

Michigan Regulatory Association:

The Veterans Alliance for Holistic Alternatives is aware of the FDA Randomized Controlled Trials examining the use of cannabis by Veterans who suffer from PTSD. I am aware that these trials have been conducted by the Scottsdale Research Institute and sponsored by the Multidisciplinary Association of Psychedelic Studies (MAPS).

As the Executive Director for the Veterans Alliance for Holistic Alternatives, I understand that Dr. Sisley will be serving as the Principal Investigator for the new FDA Phase 2 Trial examining inhaled Cannabis for treating Veterans with both PTSD and pain. As a Veteran Service Organization that assists Veterans in need throughout the United States, we are incredibly supportive and very eager to assist in Dr. Sisley's recruitment efforts to identify Veterans that meet the basic inclusion criteria.

In MAPS' last VETS/Cannabis FDA phase 2 trial, thanks to the vigorous help of veteran service organizations, Dr. Sisley was able to reach the target enrollment within the requested timeline despite zero cooperation from the local Phoenix VA hospital. VAHA feels confident that she can reach that target enrollment once again, and we will be standing by to assist in all ways possible.

Sincerely,

Gary P. Hess
Executive Director
Veterans Alliance for Holistic Alternatives
www.vahahealth.com

END APPLICANT RESPONSE

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: Rick Doblin 7/15/2021

Authorized Signatory, Rick Doblin Date
Executive Director
Multidisciplinary Association for
Psychedelic Studies (MAPS)

ATTACHMENT A: SAMPLE VMR BUDGET

Submission Date: July 16, 2021

Selected Applicant's Grant Number: _____

The numbers below are actual proposed budget amounts for the proposal.

Line Item	Budget Category	TOTAL
1	**Administrative Expenses**	
2	**Administrative Personnel (Grant Administration Staff)**	
3	*Salary*	
4	Rick Doblin, Ph.D. MAPS Executive Director	Included in indirect
5	Drew House, MAPS Interim Chief Financial Officer	Included in indirect
6	Jami Murphy, MAPS Financial Controller	Included in indirect
7	Andrew Septimus, MAPS PBC Chief Finance Officer	Included in indirect
8	Ryan Hudgins, MAPS PBC Director of Finance	Included in indirect
9	Mike Ruggles, MAPS PBC Financial Analyst	Included in indirect
10	Jane Zahniser, MAPS PBC Program Analyst	Included in indirect
11	Judy Calkins, MAPS PBC Financial Controller	Included in indirect
12	Desra Diehl, MAPS PBC Staff Accountant	Included in indirect
13	Erica Scott, MAPS PBC Director of People & Culture	Included in indirect
14	Michelle Lacy, MAPS PBC HR Senior Manager	Included in indirect
15	Jamelia Avalos, MAPS PBC HR Manager	Included in indirect
16	Christopher White, MAPS PBC Director of IT	Included in indirect
17	Larry Narachi, MAPS PBC IT Manager	Included in indirect
18	Andrew Marty, MAPS PBC IT Support Technician	Included in indirect
19	Corine de Boer, MAPS PBC Chief Medical Officer	Included in indirect
20	Berra Yazar-Klosinski, MAPS PBC Chief Scientific Officer	Included in indirect
21	Rebecca Matthews, MAPS PBC Chief Clinical Operations Officer	Included in indirect
22	Jay Nair, MAPS PBC Senior Director and Head of CMC	Included in indirect
23	Allison Coker, MAPS PBC Regulatory Affairs Manager	Included in indirect
24	**Total Salary**	$ -
25	*Fringe Benefits*	
26	Rick Doblin, Ph.D. MAPS Executive Director	Included in indirect
27	Drew House, MAPS Interim Chief Financial Officer	Included in indirect
28	Jami Murphy, MAPS Financial Controller	Included in indirect
29	Andrew Septimus, MAPS PBC Chief Finance Officer	Included in indirect
30	Ryan Hudgins, MAPS PBC Director of Finance	Included in indirect
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39	Larry Narachi, MAPS PBC IT Manager	Included in indirect
40	Andrew Marty, MAPS PBC IT Support Technician	Included in indirect
41	Corine de Boer, MAPS PBC Chief Medical Officer	Included in indirect
42	Berra Yazar-Klosinski, MAPS PBC Chief Scientific Officer	Included in indirect
43	Rebecca Matthews, MAPS PBC Chief Clinical Operations Officer	Included in indirect
44	Jay Nair, MAPS PBC Senior Director and Head of CMC	Included in indirect
45	Allison Coker, MAPS PBC Regulatory Affairs Manager	Included in indirect
46	**Total Fringe Benefits**	$ -
47	***Total Administrative Personnel***	$ -
48	**Administrative Supplies, Materials, and Equipment**	
49	10% Allocation for cost of administrative information systems	Included in indirect
50	10% Allocation of Clinical Trial Insurance Policy premium	Included in indirect
51	***Total Administrative Supplies, Materials, & Equipment***	$ -
52	**Administrative Contractual Services**	
53	Does not apply	$ -
54	***Total Administrative Contractual Services***	$ -
55	**Administrative Travel (Grant Administration Staff)**	
56	Does not apply	$ -
57	***Total Administrative Travel***	$ -
58	**Total Administrative Expenses**	$ -
59	**VMR Program Expenses**	
60	**VMR Program Staff**	
61	*Salary*	
62	Open Position, MAPS PBC Clinical Program Manager	[redacted]
63	Julie Blaisdell, MAPS PBC Regulatory Operations Specialist	[redacted]
64	Scott Hamilton, MAPS PBC Director of Biostatistics	[redacted]
65	Julie Wang, MAPS PBC Senior Clinical Data Scientist	[redacted]
66	Open Position, MAPS PBC Senior Manager CMC	[redacted]
67	Open Position, MAPS PBC Clinical Data Manager	[redacted]
68	Michelle Pleshe, MAPS PBC Director of Data Management & Services	[redacted]
69	Open Position, MAPS PBC Independent Rater Program Manager	[redacted]
70	Open Position, MAPS PBC Medical Monitor	[redacted]
71	**Total Salary**	$1,675,069
72	*Fringe Benefits*	
73	Open Position, MAPS PBC Clinical Program Manager	[redacted]
74	Julie Blaisdell, MAPS PBC Regulatory Operations Specialist	[redacted]
75	Scott Hamilton, MAPS PBC Director of Biostatistics	[redacted]
76	Julie Wang, MAPS PBC Senior Clinical Data Scientist	[redacted]
77	Open Position, MAPS PBC Senior Manager CMC	[redacted]

78	Open Position, MAPS PBC Clinical Data Manager	[redacted]
79	Michelle Pleshe, MAPS PBC Director of Data Management & Services	[redacted]
80	Open Position, MAPS PBC Independent Rater Program Manager	[redacted]
81	Open Position, MAPS PBC Medical Monitor	[redacted]
82	**Total Fringe Benefits**	$452,269
83	***Total VMR Program Staff***	$2,127,337
84	**VMR Personnel Program Staff**	
85	*Salary*	
86	Does not apply	
87	**Total Salary**	$ -
88	*Fringe Benefits*	
89	Does not apply	
90	**Total Fringe Benefits**	$ -
91	***Total VMR Personnel Program Staff***	$ -
92	**VMR Supplies, Materials, & Equipment**	
93	Costs of Information Systems Related to VMR Functions	$161,681
94	Clinical Trial Record Retention and Archival	$315,000
95	Water Pipes for cannabis inhalation for clinical research sites	$16,950
96	Magazine with 8 Dosing capsules for cannabis for clinical research sites (contingency)	$6,394
97	Sharps Containers for cannabis for clinical research sites (contingency)	$3,996
98	Cannabis Dosing Capsules for clinical research sites (contingency)	$401,200
99	Mighty Vaporizer for cannabis inhalation for clinical research sites (contingency)	$127,200
100	Filling Set for 40 Dosing Capsules for cannabis for clinical research sites (contingency)	$900
101	Cannabis Drug cost	$50,000
102	Central Reader for Digital ECG Data	$111,110
103	Outcome Measure Licensing Fees	$50,740
104	IRB Fees	$72,000
105	Study Closeout Fees	$6,000
106	iPad Devices	$9,900
107	Oura Ring Biometric Surveillance Device	$160,000
108	Data Service Charges	$48,600
109	Recruitment Website	$165,000
110	***Total VMR Supplies, Materials, & Equipment***	$1,706,670
111	**VMR Contractual Services**	
112	Clinical Site 1: Ann Arbor VAMC in Ann Arbor, Michigan	$1,099,840
113	Clinical Site 2: Functional Pain & Rehabilitation Service in Detroit, Michigan	$1,135,708
114	Clinical Site 3: James A. Haley VAMC in Tampa, Florida	$760,885
115	Clinical Site 4: Scottsdale Research Institute in Phoenix, AZ	$1,589,500
116	Clinical Site 5: TBD, Michigan (with contingency)	$1,403,901
117	Clinical Site 6: TBD, Michigan (with contingency)	$1,403,901
118	Contract Research Organization	$3,194,762
119	GMP Cannabis Packaging and Processing of Syqe Inhaler	$360,000

120	WCG Analgesic Solutions, Inc. – Placebo Response Reduction Training	$280,820
121	Quantified Citizen - Mobile Application	$79,700
122	***Total VMR Contractual Services***	$199,582
123	**VMR Travel (VMR Staff)**	
124	Investigator Meeting transportation	$33,000
125	Investigator Meeting Meals	$5,775
126	Investigator Meeting Lodging	$14,850
127	Investigator Meeting Venue	$40,000
128	***Total EAP Travel***	$93,625
129	**VMR Other**	
130	Independent Rater Pool	$ 748,800
131	***Total EAP Other***	$748,800
132	**Total VMR Program Expenses**	**$15,985,449**
133	**Total Direct Cost**	**$15,985,449**
134	*Indirect Cost (0.100000)*	$1,598,545
	TOTAL PROJECT COST	**$17,583,994**