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

VETERAN MARIJUANA RESEARCH (VMR) GRANT PROGRAM

2022

REQUEST FOR PROPOSALS

VETERAN MARIJUANA RESEARCH (VMR) GRANT

RESPONSE DOCUMENT

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

PART V: INFORMATION REQUIRED FROM APPLICANT(S)

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

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

V-A Identification of Organization

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

BEGIN APPLICANT RESPONSE

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Field to Healed

12622 N 81st Street

Scottsdale, AZ, 85260

United States of America

Federal Identification Number: 822455297

Telephone: 480.326.6023

Fax: 480.935.6512

Percentage located in Michigan: 25%

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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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Suzanne Sisley, M.D.

Telephone: 480.326.6023

Fax: 480.935.6512

ssisleymd@gmail.com

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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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Field to Healed (F2H) is a veteran-led cannabis cultivation and 501(c)(3) non-profit associated with the Scottsdale Research Institute Foundation (SRI), a Phoenix, Arizona based clinical trials site. F2H is in the public interest of furthering the advancement of novel whole plant and fungi clinical and scientific research in first-responders and military veterans in the United States. Through its non-profit endeavors, F2H strives to conduct high quality, controlled scientific studies intended to ascertain the general medical safety and efficacy of cannabis and cannabis products and examine various forms of cannabis administration. F2H benefits from its association with SRI, who conducted the first and only federally-authorized Randomized Controlled Trial study of inhaled whole cannabis flower for Post-Traumatic Stress Disorder (PTSD) for military veterans in the United States. SRI holds an active contract with the United States Drug Enforcement Agency for the manufacture and supply of cannabis for research purposes (see attachments). This status and partnership with F2H allows for the direct supply of medical-grade cannabis for clinical studies.

This study will assess the impact of high THC cannabis use for the treatment of chronic pain that has not responded to conventional pharmacological treatment among United States veterans in an outpatient setting, and will measure any potential reductions in pain and in daily opioid use measured daily morphine equivalents. Secondary measures will also assess impact on sleep quality, as well as quality of life. Suicidal ideation will also be ascertained throughout the study. The study population will be military veterans ≥ 18 years of age with a confirmed diagnosis of chronic pain from any cause for at least 6 months. The study will be a randomized, parallel design, placebo controlled study that will recruit 300 participants primarily in Michigan and will include one site in Arizona. The study will have a 2 week- screening period, an 8 week randomized treatment period (a baseline visit at the outset, two assessments during active treatment, and one end-of-treatment visit), and a 2 week- follow-up period. Since American veterans experience higher prevalence and more severe pain than non-veterans, leading to diminished quality of life (particularly for those who are young and middle-aged) this clinical trial aligns with Michigan's VMR Grant Program's goal of establishing the medical potential and efficacy of cannabis as treatment for the medical concerns of the U.S. armed services veterans, a population affected by high rates of chronic pain resulting from occupational hazards, which directly result in subsequent risk of suicidality, and opioid dependence and Opioid Use Disorder stemming from traditional pharmacological treatments. The study design is outlined in the below schematic.

People with chronic pain may be at increased risk for suicidal ideation and behavior. Lifetime prevalence of suicidal ideation in people with chronic pain is about 20%, and between 5% and 15% for suicide

attempts (Racine 2018) (Tang and Crane 2006). People with moderate or severe pain are three times more likely to have suicidal ideation (Heer et al. 2020) About 9% of Americans who died by suicide had chronic pain (Petrosky et al. 2018). Factors such as frequent pain episodes, longer pain duration, chronic pain-related conditions, pain-related sleep problems, comorbid medical or mental health conditions, poorer perceived mental health, and higher levels of pain-related catastrophizing may increase suicide risk (Racine 2018) (Tang and Crane 2006) (Brown, Lynch, and Cheatle 2020)

Between 10% and 46% of Veterans and active duty service members with chronic pain have a depressive disorder and 66% of Veterans receiving treatment for posttraumatic stress disorder (PTSD) have a chronic pain condition.(Vallerand et al. 2015) Suicidal ideation among Veterans is associated with PTSD and the interference of pain in daily activities and function. (Blakey et al. 2018)

People with chronic pain are overrepresented in the Veteran population and are at increased risk for suicide. Addressing chronic pain with Veterans is important due to its link with mental health conditions and suicidal behavior. Treatment of chronic pain and any mental health conditions can improve health outcomes and reduce or eliminate suicidal ideation and behavior. Improving pain management and functioning among patients with chronic pain is critical for reducing Veteran suicides. With proper pain management, suicide risk among military veterans may be reduced, while helping them improve their overall quality of life.

Chronic pain in U.S. veterans leads to poor quality of life, contributes to other physical and mental health problems, and impairs sleep quality. The therapeutic benefits and potential risks of whole cannabis flower inhalation for the treatment of veterans suffering from chronic pain have received limited research attention. This randomized, placebo-controlled, parallel-group study therefore aims to address this field of research. The study is designed to be consistent with the goals of this grant program, which is to explore and evaluate the potential of medical cannabis for treatment of medical conditions such as chronic pain in U.S. veterans. In addition, this study will also track potential reduction in opioid use among veterans suffering from chronic pain during the 8-week study period. The results of this study will make an important contribution to our knowledge on safety and efficacy of whole cannabis flower inhalation and will be essential in determining the potential use of medical cannabis to alleviate chronic pain and thereby improve the quality of life for veterans.

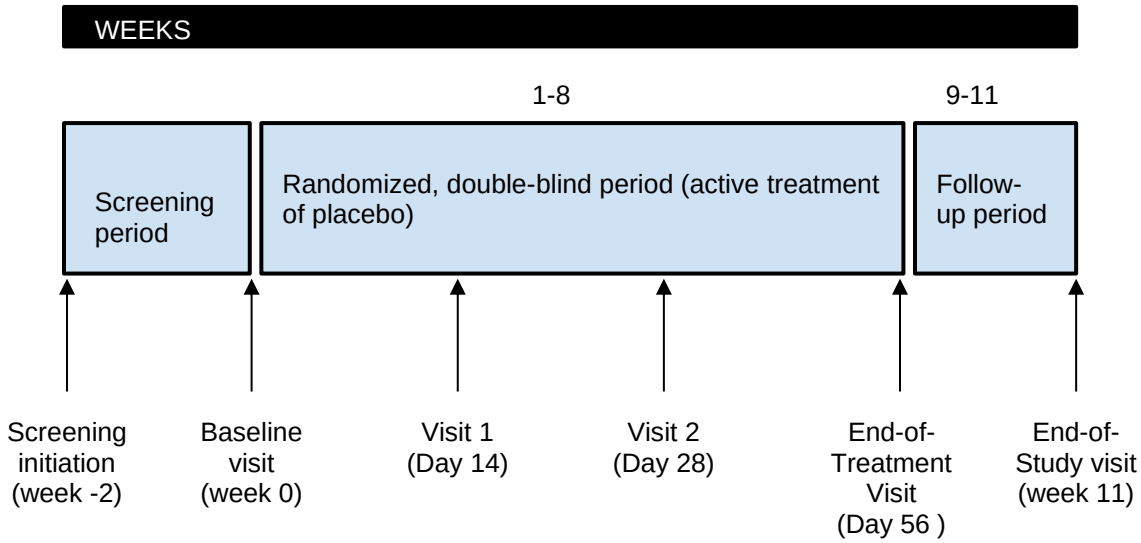

Figure 1. Clinical Trial Timeline Schematic

We have identified four obstacles related to the conduct of this clinical trial based on SRI's previous experience and our plan to address the obstacles:

1. Recruitment, enrollment and retention of veteran participants.

   There will be a recruitment and retention plan created to support the recruitment and retention of veteran participants in this clinical trial. We will work with the Veteran Administration (VA) network and Veteran Service Organizations that will help to support referrals into this clinical trial. Clinical trial sites for this study are located in Michigan, and Phoenix, Arizona and will be supervised by researchers with extensive and successful clinical trial experience including experience with this population - please see the attached Letters of Support provided at the end of this application. In addition, the recruitment plan will include strategies to enhance the recruitment of diverse populations including veterans that are women, and diverse race, ethnicity and age. We have included a marketing budget in an effort to reach diverse veteran populations and include print advertisements that are specifically geared to veteran populations including the use of digital marketing allowing the opportunity to prescreen veteran participants online (this a successful tool being used for recruitment and increasing the pre screening abilities of the sites).

   We will engage veteran advisory and representation throughout the clinical trial process including input from the protocol development through to study conduct. Using military veterans feedback on study interventions, this proposal reflects real-world applications of medical cannabis, promoting a naturalistic approach that has good external validity. Additionally, the preferences and considerations of U.S. veterans in high esteem - it is critical to utilize feedback from target populations in study design and protocol, to ensure that future medical interventions account for the real-world behaviors and experiences of those whom the field aims to benefit. In addition, collaboration with the research sites, researchers including pain specialists and psychiatrists with experience with the indication and population to ensure the study is scientifically strong but also practical to implement with the intended population.

   Working with experience sites will help as based on previous experience it will take pre-screening of 4,000 potential veterans for study eligibility, formal phone-call screening of 1,200 eligible veteran participants, formal in-lab screening of 600 eligible participants, to ultimately enroll 300 veterans.

2. Obtaining high quality Investigational Product for the clinical trial.

   In the previously funded government funded PTSD clinical trial in veterans, there was a high placebo effect, which may have been caused by the low quality and potency of federally legal cannabis that was used. The product to be used in this clinical study is a high THC dried cannabis flower grown organically with a solar tube system, allowing for full enrichment of the outdoor sun in F2H's growing facility. U.S. veterans comprise the growing team, a practical implementation of the organization's mission to both involve and assist veterans with the advancement of medical cannabis research. Inhaled high THC cannabis is a preferred method of consumption among veterans, as demonstrated in several cross-sectional and observational studies to date and in focus groups conducted by Dr. Sisley (Loflin et al., 2019; Bonn-Miller et al., 2022). These products are commonly used by army veterans to treat physical and mental health symptoms, leading to greater reductions in PTSD symptoms when smoked cannabis flower with a ~20% THC concentration is used. (Bonn-Miller et al., 2022). As aforementioned, Dr. Sue Sisley conducted two focus groups where insights from Michigan military veterans were gained on study design and the study intervention. Focus group participants were presented with eight different varieties of cannabis flower certificates of analysis (COAs) that F2H of SRI is currently cultivating under their DEA Schedule 1 license, and were asked for their critique of the chemical profiles to learn more about what properties of whole cannabis flower they prefer to use for medical purposes. Veterans indicated a preference for high THC cannabis. In keeping with these observations, and with the previous experience gained through the randomized controlled trials where different THC concentrations have been studied for the treatment of PTSD, and where Dr. Sisley has participated as an investigator, the high THC dry flower product was selected as the study intervention to harness the analgesic potential that inhaled THC has demonstrated in preclinical and clinical study populations and to provide veterans with a preferred method of administration that is highly acceptable and that will ensure compliance with the study procedures. This clinical trial provides for an ad libitum use of up to 2 grams per day of dry cannabis flower, an upper limit that is consistent with allowances for previous randomized controlled trials and already approved VA grants, and in consideration of the outpatient setting for self-administration and the

Schedule 1 status of the study drug.

3. High Placebo Effect

We will be contracting the services of WCG Analgesic Solutions, Inc. for placebo response reduction training. Due to the sizable placebo effect this service is necessary. Investigators, therapy teams, and all study staff will be trained prior to study by the CRO 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).

4. Regulatory Approvals

We will assess a CRO that has the expertise in conducting cannabis clinical trials and a track record for obtaining FDA regulatory approval. In addition, we have and will select sites and PIs that have both experience with clinical trials, including therapeutic experience with the veteran population.

References

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

F2H, is the sponsor of the study and will be responsible for the Investigational New Drug (IND) filing with the U.S. FDA for this cannabis clinical trial and F2H will be responsible for the Investigational Product (Medical grade high THC cannabis flower and placebo) to be supplied to each of the research sites for this clinical trial.

F2H the sponsor will work with the awarded CRO to manage this clinical trial. These tasks and duties include protocol design, initiation, management, coordination, continuation, and conclusion of the clinical trial. The CRO will also manage the Regulatory Submission to the U.S. FDA. Compliance with the highest standards of clinical research, study protocol, and federal/state regulations will be ensured and monitored by both F2H and the CRO. F2H and the CRO will oversee the overall quality of study conduct and ensure adherence to GCP. F2H has partnered with private practice community clinical trial sites to accomplish these goals. At every level, F2H ensures sponsor oversight of safety, and manages the conduct of the study in line with the study budget.

TASKS AND RESPONSIBILITIES	Sponsor (F2H)	CRO (TBD)	RESEARCH SITES
FDA IND Submission (including Pre-IND Meeting)	X Responsible	X Responsible	
Investigational Product (Testing, IB etc.)	X Responsible	Oversight	
Study Design and Protocol Development (with input from KOLs, PI's, CRO, Veteran groups and advisory)	X	X	X Provides input
Ethics Approval	Oversight	X	
Quarterly Reporting and Management of Grant Funding	X Responsible	X Support managing study costs	
Participant Recruitment, Enrollment and Study Conduct	Oversight	Oversight	X
Project Management (Project Plans include Project and Communication Plan, Risk Mitigation Plan, Recruitment Plan, Monitoring Plans etc.)			
Data Management	Oversight	X	X
Study Monitoring	Oversight	X	X Participants in monitoring activities
Clinical Report Development	Oversight	X	
Publication Development (as per publication committee grant guidelines)	TBD		

Objective 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.

F2H is committed to undertaking clinical trials with rigorous standards. F2H as an organization values high product quality, safety and efficacy standards, and maintains strict compliance with all standards set by the World Health Organization, the United States Food and Drug Administration, and all federal and global regulatory standards. F2H adheres to Good Clinical and Laboratory Practice standards, as well as Good Manufacturing Practice standards (through its affiliation with SRI). F2H is dedicated to partnering with vendors and subcontractors adhering to ethical and compliant business practices. Through its partnership with SRI, F2H receives its medical cannabis study drugs that are locally manufactured, packaged, and tested under strict protocol adherence and by a qualified team (see Section V-G, Personnel; F2H Organizational Chart; F2H Cultivation Team).

F2H, in partnership with the CRO, is responsible for establishing the organizational structure, resource allocation, and development of guidelines that assure all quality measures conform to regulatory requirements. Management of quality throughout all stages of the clinical trial process will be the responsibility of both F2H and the CRO. F2H and the CRO will together communicate to the entire clinical trial team across sites the importance of meeting statutory and regulatory requirements, procedures for data management, and pipeline of reporting compliance issues.

F2H will select a subcontracted CRO through a competitive bidding process. The CRO will provide support throughout the entire clinical trial, including training and supervision of clinical trial site teams, assistance with transport and shipping of the study drug to Michigan from Arizona, monitoring of data quality and integrity, creation and maintenance of regulatory files, and safety reporting as per GCP and regulatory requirements. Development and implementation of monitoring plans, oversight of Schedule 1 drug accountability, and site start-up, activation, and closing will be responsibilities of the CRO. F2H and the CRO will work together to subcontract a qualified electronic data system service, for secure storage of study data as per regulatory requirements.

Principal Investigators and clinical trial staff will be trained prior to study commencement by the CRO and Dr. Sisley of F2H on study protocol, procedures, safety considerations, and infrastructure. To address

previously observed placebo response rate in a study investigating cannabis as treatment for PTSD (Bonn-Miller et al. 2021), F2H will subcontract Analgesic Solutions, Inc. to provide Placebo Response Reduction and Accurate Symptom Reporting Training to Principal Investigators, clinical trial site staff, and study participants through a Learning Management System. Due to the chronic pain objective of the proposed study, implementation of the Placebo Response Reduction service is an important risk mitigation tactic, and ensures a high-powered study while minimizing potential confounds.

Each clinical trial site will recruit study participants from local veteran populations, treat participants, and complete remote data entry into the electronic database. CRO personnel will meet regularly with Principal Investigators throughout the study, monitor compliance at each site, and routinely and remotely monitor data. Each monitoring visit by the CRO at clinical trial sites will involve source data verification to ensure compliance, compliance checks on the electronic data management system, validating source records, and monitoring drug accountability records. The CRO overseen by F2H will ensure the secure electronic database is auditable at any time. All key personnel will be involved in final data clean up and database lock, as per federal requirements. A qualified statistician from the CRO will perform data analysis with input and review from key personnel. Upon completion of the study, the CRO will perform closing visits at each site and will manage the analysis and the final report process to complete FDA reporting requirements. F2H will work with qualified personnel of the CRO to publish the findings from this trial.

Objective 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.

As the sponsor, F2H is primarily responsible in providing fiscal control and financial accounting procedures that ensure the grant funds will be utilized with full accountability, and to ensure all expenditures and costs charged to the grant are specifically allocable to the grant. F2H and the CRO will track grant finances (income and expenses) via QuickBooks software. F2H and the CRO will obtain financial management services including a bookkeeper, financial controller, and program accountant - these administrative personnel will maintain and administer the extra records and accounting necessary to manage the program requirements. Funds will be maintained in a non-interest-bearing operating account. Presently, F2H does not meet the financial threshold of Federal funding necessary to perform a Single Audit as required by OMB Circular 200.36 (A-133 Audit; threshold of $750,000 in federal funds within one fiscal year) - however, if the grant is awarded, F2H will update its auditing plans to allow for a Single Audit. All documentation to support administrative cost sharing will be retained.

Objective 4. Describe your agency's **data security plan**.

F2H is committed to ensure protection of participant research data and will ensure during study start up that site feasibility is conducted to ensure that all of the research sites have training and SOPS in place to ensure data security. The protocol will also include an area in which measures to ensure data security are included and consideration for data security will be considered with the selected Clinical Trial Management System. During all monitoring visits at the research sites, data security will be reviewed to ensure adherence with data security as per site SOPs and Protocol..

During study set up and monitoring visits, the CRA will ensure that all clinical trial staff are aware of their individual responsibilities to properly use computer resources and adhere to data privacy standards. Any violation of established policies (be it intentional or due to negligence) or improper use of company computers will result in corrective action. All clinical trial staff are also aware that any work or communications completed on company computers is subject to monitoring, audit, and review. F2H uses Information Technology resources in cost-effective ways that ensure the safety of member data and promote accuracy and efficiency of clinical trial data.

All data collected for this project will not include any identifiable information and each participant will be assigned an individual prescreening, screening and randomization codes. These codes will be kept in a master file, separated from the identifiable information, by using a different passcode and kept in a

different folder in a password protected server. In addition, this study will ensure blinding procedures and include both a blinded and unblinded Monitor. All of the data for this project will be collected specifically for research purposes. Hard copy files will be kept in locked file cabinets within locked offices. Electronic data will be kept in a secure folder on a secured, password protected server, with access restricted to staff for this specific research study. Participant numbers without personal identifiers assigned to each participant will be the only means by which collected information is labeled. The master code is the only list that will link the names of the participants with their participant numbers and will be kept in a secure, password- protected computer account on a separate drive from research coded data and will be accessible to only personnel authorized.

The awarded CRO will be responsible to develop a data management plan that will include data security including appropriate backup and retention of research data. They will also ensure vendor assessment and selection of a centralized, FDA-compliant (21 CFR Part 11 compliant) database, which will be auditable at any point during or following completion of the study.

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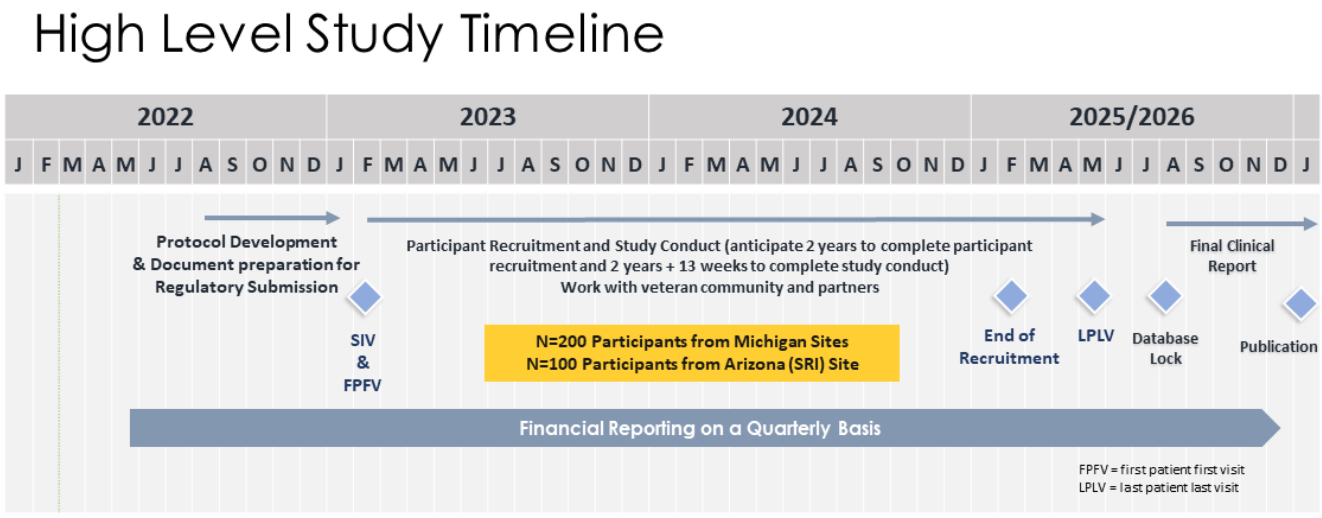
1. Provide for the **coordination and overseeing of clinical trial(s) to determine the efficacy of marijuana in treating the medical conditions of U.S. armed services veterans** and preventing veteran suicide.

The study is estimated to take 42 months to complete and will commence on August 1, 2022 and continue through to January 2026. This multi-site study will be conducted at 3 clinical trial sites with two sites in Michigan and 1 site outside Michigan (Arizona). Through their affiliation with patients from VA networks or Veteran Service Organizations, each clinical trial site will be able to recruit veterans. CRO personnel will qualify and activate the clinical trial sites for this study. The preparation and conduct of Investigator

Meetings with input from WCG Analgesic Solutions trainers on Placebo Response Reduction and Accurate Symptom Reporting Training will be carried out by CRO personnel. A central Investigator Meeting involving training on study protocol, procedures, safety considerations, data management, and infrastructure will be attended by F2H personnel and other clinical trial site personnel. Prior to commencement of this study, all study sites will be visited by CRO personnel who will ensure site readiness and staff training. Each study site will contain appropriate laboratory space for conducting participant screening, interviews, and assessments, as well as a space outfitted with appropriate ventilation systems for the on-site administration and inhalation of smoked cannabis flower. All medical-grade cannabis will be provided by F2H, via its affiliation with the SRI (which holds a DEA Schedule 1 license for the production, manufacture, and distribution of medical-grade research cannabis), and will be shipped to and stored by each site in compliance with DEA requirements. Eligibility requirements for this clinical trial are designed to recruit veterans suffering from chronic pain, who may or may not have previously, or currently, experienced mild to moderate risk of suicidality, and study protocols include measures to mitigate suicide risk and properly monitor and manage such risk during the trial. F2H's experienced clinicians include Dr. Sisley and Dr. Kaplan (psychiatry), Dr. Molk (emergency medicine), and Dr. Jaffe (cardiology), who are all trained in recognizing suicidality in the veteran population, and addressing emergency concerns. Compliance with study procedures and protocols across this multi-site clinical trial will be ensured and monitored by the CRO, who will conduct regular Investigator meetings, remote data monitoring, and multiple on-site visits. The CRO will also ensure that data from each site is entered into a centralized, FDA-compliant database, which will be auditable at any point during or following completion of the study.

During the first 6 months, once the grant is awarded, F2H will promptly hire an administrator to manage the grant administration funding. Concurrently the sponsor will select and award a CRO with cannabis clinical trial management experience to oversee the clinical trial in conjunction with the sponsor. The first 6 months will be dedicated to study set up including development of study design, protocol (in collaboration with veteran associations and partners, veteran advisory, KOLs including experienced researchers such at the PIs identified at the sites, and the CRO that will have expertise in study design and protocol development. In addition The planning will include a pre-IND with FDA to discuss protocol and study design followed by IND submission to FDA. The sites will be assessed for clinical trial readiness concurrently to prepare for the conduct of the clinical trial. Based on feedback from the sites from clinical trial experience with this study population, it will take 1.5 years to 2 years to meet participant recruitment of 100 participants from each site (timeline is buffered to allow for up to 2 years for participant recruitment). It is anticipated that the final clinical report and publication will be completed by the end of 2025 and the latest by January 2026.



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

F2H has identified a strong partner in Dr. Ryan Abboud MD, who runs a private practice serving countless Michigan veterans with chronic pain, and many with opioid dependence. Principal Investigator Dr. Abboud will lead a team of investigators to undertake this study. Dr. Pranav Jagtap MD with Paradigm Psychiatry will serve as Sub-Investigators - this clinical team has extensive experience as physicians working with veterans. Principal Investigators at each study site have adequate staff to support the study activities. Principal Investigators will be responsible for overseeing the study from commencement to completion, will ensure study protocol compliance at their respective locations, and will adhere to applicable requirements. F2H 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. Subcontracting WCG Analgesic Solutions to administer Placebo Response Reduction and Accurate Symptom Reporting Training to all personnel involved in the study will ensure reductions in placebo effects and result in a higher-powered study.

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

F2H is dedicated to working closely with local, national and international regulatory agencies to provide access to high-quality, first-class cannabinoid pharmaceuticals to those critically in need of new treatments for life-threatening and debilitating conditions. Dr. Sisley, founder of F2H, served for three years as Sub-Investigator in a series of Phase 3 and Phase 4 drug development trials conducted at the Pivotal Research Center (later renamed Premier Research). These FDA-approved research studies were performed on novel psychoactive drugs with the goal to investigate the range of physiological and psychological effects of administering study drugs to adult research volunteers. Dr. Sisley also led the first FDA-approved randomized controlled trial examining safety and efficacy of smoked whole marijuana flower for treatment in veterans with severe post-traumatic stress disorder (PTSD) together with the Multidisciplinary Association for Psychedelic Studies (MAPS). Dr. Sisley has served for several years as both Sub-Investigator and Principal Investigator of various FDA drug-development trials sponsored by pharmaceutical companies through the Pivotal Research Center.

The Detroit site is led by 2 primary care physicians, Drs. Abboud and Kolender, with many years of experience managing chronic pain/opioid dependence in Veterans. They will benefit from F2H coordinating PI that will ensure site protocols are standardized and adherent to FDA/IRB rules. Dr. Abboud will be assisted by 2 co-investigators with numerous years of experience dealing with VA patients and serving on Detroit VA Pain Committee:

Dr. Kondur and NP, Kevin Cischke.

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.**

F2H is dedicated to maximizing grant dollars used to coordinate and oversee this clinical trial. F2H will also limit indirect costs to 10% of direct costs, and this requirement flows through to subcontractors of F2H. Other than the cannabis cultivation operations, F2H operates as a virtual entity, therefore administrative costs are further limited by design. Employees and contractors carrying out administrative duties work from home. As such, administrative staff do not incur travel costs for F2H's business. F2H and subsidiaries have found that operating virtually has provided numerous efficiencies and this is expected to continue through the grant period. See budget for more details.

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. One of the clinical trial sites is a busy,

holistic private practice serving a vast network of local veterans. Furthermore, one clinical trial site is located in Michigan. Other additional sites may be identified for this trial in Michigan to ensure that grant priorities are satisfied with Michigan organizations. F2H will work with organizations closely tied to veterans and veterans' programs, such as Hero Project USA, Heroic Hearts Project, Balanced Veterans Network, and AMVETS. Clinical trial sites will be responsible for obtaining IRB administrative approvals for study conduct, identifying veterans with chronic pain, 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, and conducting follow-up visits per the study protocol.

Scottsdale Research Institute: ***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.

Dr. Sisley spent three years after residency training with Premier research company conducting a variety of FDA randomized controlled trials for large pharmaceutical companies in the neuroscience area. 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 chronic pain in a veteran population. Dr. Sisley will oversee the recruitment, treatment, safety management and data collection of 100 participants in this clinical trial in her role as the Site Principal Investigator for SRI.

The Scottsdale Research Institute (SRI) is located inside a large, 8000 square-foot mixed-use building in North Phoenix. The front half includes space for conducting FDA clinical trials. The back half of the building is warehouse/industrial space for the cultivation of the cannabis flower including tissue culture lab, mother plants, vegetation room, flower room, drying and curing etc. It is located in the state of Arizona, which has a population of approximately 700,000 military veterans. Over half of these veterans reside in the largest county, Maricopa County, which is where the clinical trial site is located and is guaranteed to attract the maximum density of veteran volunteers. Over 90% of the veterans treated at SRI have both chronic pain and PTSD. The majority of these veterans report that their PTSD/chronic pain is untreated or under-treated.

F2H/SRI conducts FDA phase 1, 2 & phase 3 trials. One clinical trial already completed, MAPS MJP1, explored inhaled cannabis for military veterans with PTSD. A second, pharmaceutical-company sponsored trial, studied inhaled cannabis for treating uncontrolled pain in late stage cancer patients. F2H/SRI is currently preparing for an FDA Phase 1 safety study looking at psilocybin mushrooms for treating depression/anxiety in military veterans. In addition, F2H/SRI has completed four different observational studies using whole cannabis in different formulations including a safety study looking at cannabis edibles for insomnia

F2H and SRI both have deep ties throughout the veterans community that have been nurtured over the past 15 years. Veterans are very aware of their track record and credibility in the veterans cannabis

research realm, which enables SRI to recruit high velocity of veterans for screening into the study in the shortest amount of time requiring lower marketing/PR budget. These relationships with veteran groups have been well established from previous clinical trials and can call on this database for the purposes of this RCT.

F2H also has the unparalleled ability to manufacture its own cannabis for our own clinical trials, providing a key advantage as to not to be dependent on the lesser quality cannabis and slower processes that are common when procuring cannabis from other federally licensed institutions. It is well known among the cannabis research community that cannabis flower from the University of Mississippi in past years has been plagued with mold counts, which are greatly concerning to the Veteran community and may endanger the health of research participants. Attached to this proposal are the certificates of analysis, confirming there is no detectable mold in any of F2H batches.

Objective 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.

- CRO financial and accounting team will provide the Grant Administrator the financial reporting required and in their preferred format. F2H agrees to provide the backup detail to justify grant funds expenditure as required by the RFP. Within the accounting system, vendor lists will be kept and maintained to enable vendor and site-specific reporting within the unique class code assigned to the trial. F2H will perform an annual external financial audit. Presently, F2H does not meet the financial threshold of Federal funding necessary to perform a Single Audit as required by OMB Circular 200.36 (A-133 Audit; threshold of $750,000 in federal funds within one fiscal year) - however, if the grant is awarded, F2H will update its auditing plans to allow for a Single Audit. All documentation to support administrative cost sharing will be retained.

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

F2H is committed to pursuing U.S. FDA approval for prescription use of high THC inhaled cannabis flower for chronic pain treatment, and will work with its clinical team, SRI, and CRO to ensure the study is initiated, executed, monitored, and controlled. Together, these teams will manage financial, managerial, and clinical oversight. Dr. Sisley of F2H will be responsible for overseeing the timely execution, quality and accuracy of grant deliverables, and will work closely with co-investigators funded by this grant, if awarded.

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

- Timely analysis and communication of clinical trial results is imperative in the advancement of scientific knowledge and furthering the development and utilization of novel therapeutic techniques. Following the completion of the study, at all sites, data will be aggregated and analyzed by CRO Data Scientists, Statisticians, and Clinical Scientists. These personnel will work with study PIs in the interpretation, write-up, and publication of study results. Manuscripts arising from this study will be submitted to reputable, peer-reviewed scientific journals for consideration and publication. Measures will be taken to ensure that publications and dissemination of study results are also easily accessible to the general public, in accordance with the Open Science Principles. Presentation of study results will be pursued at national conferences. Contributions of PIs and clinical study team members will be considered and weighted in the deciding authorship on all publications and presentations of study data. Additionally, ensuring study results are available to U.S. veterans via VA networks and Veterans Groups is of great importance to F2H's mission, vision, and values. 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. F2H will not seek to copyright, patent, trademark or create trade secrets and will make all the data public in accordance with Open Science Principles.

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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.

F2H Foundation (F2H) is a veteran-led cannabis cultivation non-profit organization known for valuing the unique climatic conditions that lead to the growth of outstanding cannabis flowers. Our veterans grow in an environmentally conscious manner, under full sun, using only organic methods. They value the farm environment as much as the end product. These growing methods result in the finest cannabis, grown under the strictest standards. Our cannabis represents the quality and spirit of the veteran growers who paved this path. In the 1960s and 70s, hundreds of veterans flocked to the Emerald Triangle in search of freedom, to live a life closer to nature. A life of simplicity and harmony with their environment that reflected their beliefs. F2H prides itself on growing cannabis in small batches using sustainable and organic methods to grow premium, Clean Green Certified flower in a zero-carbon footprint farm in Phoenix, Arizona. Clean Green Certified is a program based on existing national and international agricultural standards to certify cannabis grown using sustainable, natural, and organic methods. F2H believes that every study participant should know who is growing their cannabis and where and how it is being grown. Suzanne Sisley, M.D., president and principal investigator at F2H, has extensive experience conducting clinical trials, which enables her to manage the allocated funds successfully. She co-led the first FDA-approved randomized controlled trial examining safety and efficacy of smoked whole marijuana flower for treatment in veterans with severe post-traumatic stress disorder (PTSD), together with the Multidisciplinary Association for Psychedelic Studies (MAPS), making her uniquely qualified with hands-on experience in conducting clinical trials of cannabis for treatment of veteran patients. She also led the study "Safety and Efficacy of Inhaled Cannabis For the Uncontrolled Pain Relief in Patients With Advanced Cancer". Dr. Sisley also co-led several other studies focusing on medical cannabis for chronic pain patients.

Objective 2 - F2H has not previously received grant awards from the State of Michigan. Dr. Sisley of F2H is listed as a Principal Investigator of Clinical Trial Site 4 of the 2021 VMR granted proposal by the

Multidisciplinary Association for Psychedelic Studies. Dr. Sisley is not a direct grant recipient, and dispersed funds from the 2021 VMR grant awarded to MAPS will be allocated as outlined in Line 112 of their Response Document.

Objective 3 -

F2H **Foundation**
4 Year Revenue by Source
06/1/2022
June 2018 through May 2022 Accrual Basis
Jan 2018 - May 2021
Ordinary Income/Expense

Income

41100 · Products Sales	0
41600 · Event & Conference Income	2,541
41800 · Commission Income	0
41000 · Earned Income - Other	12,307
40100 · Corporate Contributions	23,100
40200 · Foundation Contributions	54,793
40300 · Individual Contributions	11,364
40500 · Donated Goods	812,836
40600 · Bequests	0
45000 · Investment Income	0
46000 · Government Grants	120,592
42000 · Fiscal Sponsorship Income	0
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Total Income	**208,210**

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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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Suzanne Sisley, M.D., President and Principal Investigator at F2H (Site 1): Dr. Sisley serves as President of the F2H with over 14 years of experience supervising and providing direct patient care to a diverse population of adults with medical and psychiatric disorders. Dr. Sisley served for three years as Sub-Investigator in a series of Phase 3 and Phase 4 drug development trials conducted at the Pivotal Research Center (later renamed Premier Research). These FDA-approved research studies were performed on novel psychoactive drugs with the goal to investigate the range of physiological and psychological effects of administering study drugs to adult research volunteers. Dr. Sisley also led the first FDA-approved randomized controlled trial examining safety and efficacy of smoked whole marijuana flower for treatment in veterans with severe post-traumatic stress disorder (PTSD) together with the Multidisciplinary Association for Psychedelic Studies (MAPS). Dr. Sisley has served for several years as both Sub-Investigator and Principal Investigator of various FDA drug-development trials sponsored by pharmaceutical companies through the Pivotal Research Center. She has also founded the F2H Foundation, the 501(c)(3) arm of the SRI, which advocates to raise funds for non-profit research to develop drugs from natural plants and fungi and seeks to remove government barriers to plant research. Other areas of current IRB-approved research include co-investigation in studies evaluating cannabis for pain management, and cannabis as substitution therapy for opioids. In collaboration with the College of Medicine (Department of Anesthesiology and Chronic Pain) at the University of Michigan, along with Prof. Daniel J. Clauw and Kevin F. Boehnke, PhD, Dr. Sisley published several studies on cannabis as a substitute for opioid and other prescription medication dependence. Dr. Sisley recently also completed an FDA Phase 2 RCT examining safety and efficacy of inhaled cannabis flower for treating uncontrolled pain in late-stage cancer patients. Dr. Sisley also functioned as co-investigator in 2019 on a study examining the dangers of overdosing on cannabis edibles together with Prof. Josh Meisel at Humboldt State University. Dr. Sisley also received a government grant as Principal Investigator to launch and supervise an international registry for medical cannabis patients with Colorado State University Pueblo. The registry became operational in 2019 and continues to collect detailed survey data from cannabis users for both medical and recreational purposes. Dr. Sisley has also applied for DEA Schedule 1 license to manufacture cannabis and psilocybin mushrooms for SRI and F2H non-profit drug development research.

Alan G. Molk, M.D., FACEP, Sub-Investigator at F2H (Site 1): Dr. Molk serves as Sub-Investigator for F2H's Clinical trials. A Board Certified Emergency Medicine physician since 1985, Dr. Molk is a member of the American College of Surgeons and American Heart Association, and since 2015 has held an academic appointment as Clinical Assistant Professor of Emergency Medicine at the University of Arizona College of Medicine - Phoenix. In his long career as an Emergency Medicine physician, Dr. Molk has worked extensively with United States military veterans. In his practice he has addressed pain management concerns and opioid dependence in the veteran population, and maintains many connections with the community. Dr. Molk's decision to join F2H was fueled by his desire to advance the study of pain management therapeutics via clinical trials. Through his work with F2H, Dr. Molk will serve as the Sub-Investigator for Dr. Sisley's MAPS-associated clinical trial, investigating cannabis as treatment for PTSD in the veteran population (awarded funding from the 2021 Veteran Marijuana Research Grant Program).

Travis Allan Johnson, Study Coordinator for F2H and SRI: Johnson, a Certified Clinical Research Coordinator (SOCRA), has served as Study Coordinator for F2H and SRI since 2020. Johnson, an experienced clinician with extensive clinical trial experience, is a Certified Phlebotomy Technician, Credentialed Trainer with electronic health system Epic, and holds a certificate of Good Clinical Practices. Johnson joined F2H and SRI following eight years with the Arizona Alzheimer's Consortium, where he served as Lead Clinical Coordinator and contributed to three peer-reviewed research publications. He also held a position as Pure Labs AZ's Analytical Chemist and Quality Manager, working with and preparing samples for Coupled Plasma Mass Spectrometer processing. In his work with F2H and SRI, he oversees all Clinical Trials, from set-up to closing, and ensures Good Clinical Practices are followed for participant intake, enrollment, and follow-up. Johnson conducts Clinical Trial duties as per study protocols issued by Dr. Sisley (the Principal Investigator),

maintains regulatory files, and manages required regulatory submissions. Johnson will coordinate and manage the proposed study at the F2H site in Arizona.

Kady Bentz, MS, Unblinded Study Coordinator for F2H and SR (Site 1)I: Kady Bentz, a Clinical Research Associate and Certified Clinical Research Coordinator (SOCRA), works at Barrow Neurological Institute-CRO, AZ, as a Clinical Research Associate where she is responsible for all aspects of site management and trial administration, for working with sites during study start up, provide ongoing training, site initiation visits, remote monitoring, interim field monitoring and close out visits. She is also responsible for evaluating clinical data documentation, monitoring safety and conduct of study to ensure investigator and site compliance with study protocol, as well as for preparing accurate and timely monitoring reports, etc. Kady Bentz worked at SRI as a Professional Clinical Research Coordinator, where she was responsible for the chain of custody and accurate accountability of investigational product, all study devices, where she served as primary unblinded coordinator for complex clinical studies, managed all clinical supplies and the inventory, coordinated patients and conduct of trials and performed ECGs, obtained vital signs, obtained biologic samples, and performed any other applicable duties per protocol, etc. She has also worked as a Senior Clinical Research Coordinator in Phoenix Children's Hospital, AZ; as a Clinical Research Coordinator at Arizona Arthritis and Rheumatology Research, PLLC, at Imaging Endpoints LLC, at Bioscreen Clinical Services, and at Phoenix Medical Research Institute, AZ. She completed her M.S. in Clinical Research Management in 2016.

Cherissa Jackson, Chief Medical Executive AMVETS, F2H Scientific Advisory Board: Cherissa Jackson served 23 years of active-duty military service with 10 of those years as an U.S. Air Force Nurse. She is a veteran of both Operation Enduring Freedom and Iraqi Freedom, having served a total of 3 combat deployments where she honed her expertise as a battlefield clinician. She is known as "America's Combat Nurse" because of her extensive combat experience. Following her honorable service, Jackson became an ambassador and advocate for persons with Post Traumatic Stress Disorder (PTSD). She was inducted into the SHEROES United Organization Hall of Fame and traveled to Rome, Italy in November 2016 in order to collaborate with the Vatican, the Nation of Congo, and the city of Amatrice, Italy to help advance a global discussion on eliminating stigmas associated with PTSD. She has a non-profit that saves the lives of women from cervical cancer called "Project Give Hope" and has traveled internationally to Uganda in 2017, and 2018 and will be traveling to Nigeria in October 2021. Jackson is the author of "At Peace Not in Pieces," a bestselling memoir that outlines her principles of coping with her own PTSD challenges as a combat veteran and nurse. She was also named one of "25 Individuals of Influence" in the June 2018 issue of PTSD magazine and recently joined the HillVets 100 list of top influencers of 2018. Cherissa also won the "Daily Record Top 100 Maryland Women for 2016" for her efforts with PTSD. Recently Cherissa was awarded the first "Passion Award" at the AVB 2019 (American Veterans Ball). She is 2020's recipient of "The Vettys" (Veterans Award) for excellence in Mental Health. This year, she won the "Star Nurses Nightingale Award" amongst 600 nominees in September 2020. The award was a collaboration between the Washington Post and American Nurses Association.
She joined AMVETS on February 1, 2019 as Chief Medical Executive and leads the organization's HEAL Program, which strives to confront the risk factors that lead to crisis and veteran suicide. She uses her experience to lead the organization's effort to address issues related to women veterans and champion legislation that improves access to quality healthcare. She has conducted several Focus groups around women veterans and LGBT+ communities. She and her team launched a Suicide Prevention Training in September 2019 during Suicide Prevention Month. Most recently, Cherissa created the first ever "Veterans Alternative Healthcare Summit" on June 27, 2021 that discussed the efficacy of cannabis and how cannabis can save the lives of Veterans. This was a virtual conference that showcased how AMVETS is speaking out loudly and boldly about our support of cannabis. No other VSO has tackled this discussion like Cherissa. There were over 21.8K engagement interactions on this one-day virtual conference. Cherissa holds a Bachelor's of Science in Nursing degree from the Medical University of South Carolina and recently got accepted into the University of Maryland Masters of Science program in Medical Cannabis Science and Therapeutics.

Ryan Abboud, D.O., Principal Investigator (Site 2): Dr. Ryan Abboud is board-certified in Family Medicine and specializes in Prevention and Lifestyle. He employs evidence-based and holistic approaches from the best in Functional and Integrative Medicine in his private practice to prevent heart attacks and strokes. Dr. Abboud is passionate about managing pain in safe and non-addicting ways. He has spent the last ten years of clinical training and practice to help curb the opioid epidemic, he utilizes acupuncture, ketamine therapy, and buprenorphine to help people who suffer from pain and addiction. Dr. Abboud has done award-winning research in mental health and has been an advocate for veterans ever since working at the VA during his residency. This long-standing interaction with military veterans has made him proud to continue to assist in this cause. He is passionate about using food as medicine to optimize metabolic function and has been seeking alternative treatments in treating mental health conditions, such as using plant medicines and meditative techniques in lieu of opioids.

Malcolm Cavin, Lab Technician (Site 2): Mr. Cavin received his B.Sc. in Biomedical Engineering from Arizona State University. He has worked as a Clinical Conduct Associate for Celerion (Tempe, Arizona) since 2017, with responsibilities including phlebotomy, ECG, vital monitoring, and collection and processing of tissue samples, all with strict adherence to GCP. In the proposed study, Mr. Cavin will work as a Lab Technician and perform similar duties as per protocol, under PI Dr. Abboud, at Site 2 in Michigan.

Jane E. Kaplan, M.D., Psychiatrist On-Call: Dr. Jane Kaplan completed her M.D. in 2001 in Creighton University School of Medicine, Omaha, NE, and her B.A. (cum laude) and B.S. (cum laude) in 1995 at Loyola University, Chicago, IL. Kaplan did her postdoctoral training as a resident from 2001 to 2004 at the Psychiatry, Harvard Longwood Psychiatry Residency Training Program in Boston, MA, from 2004 to 2006 as fellow in the Child and Adolescent Psychiatry at Massachusetts General Hospital/McLean Child and Adolescent Psychiatry Residency Training Program, Boston, MA, and from 2005 to 2006 as chief resident at the Massachusetts General Hospital/McLean Child and Adolescent Psychiatry Residency Training Program. From 2006 to 2007 she was responsible as instructor in Psychiatry, Harvard Medical School, and from 2012 onwards she works as Assistant Clinical Professor of Psychiatry at Creighton University School of Medicine, Phoenix Regional Campus in Phoenix, AZ. Dr. Kaplan also works at Headstrong/Weill Cornell School of Medicine for trauma care for Veterans.

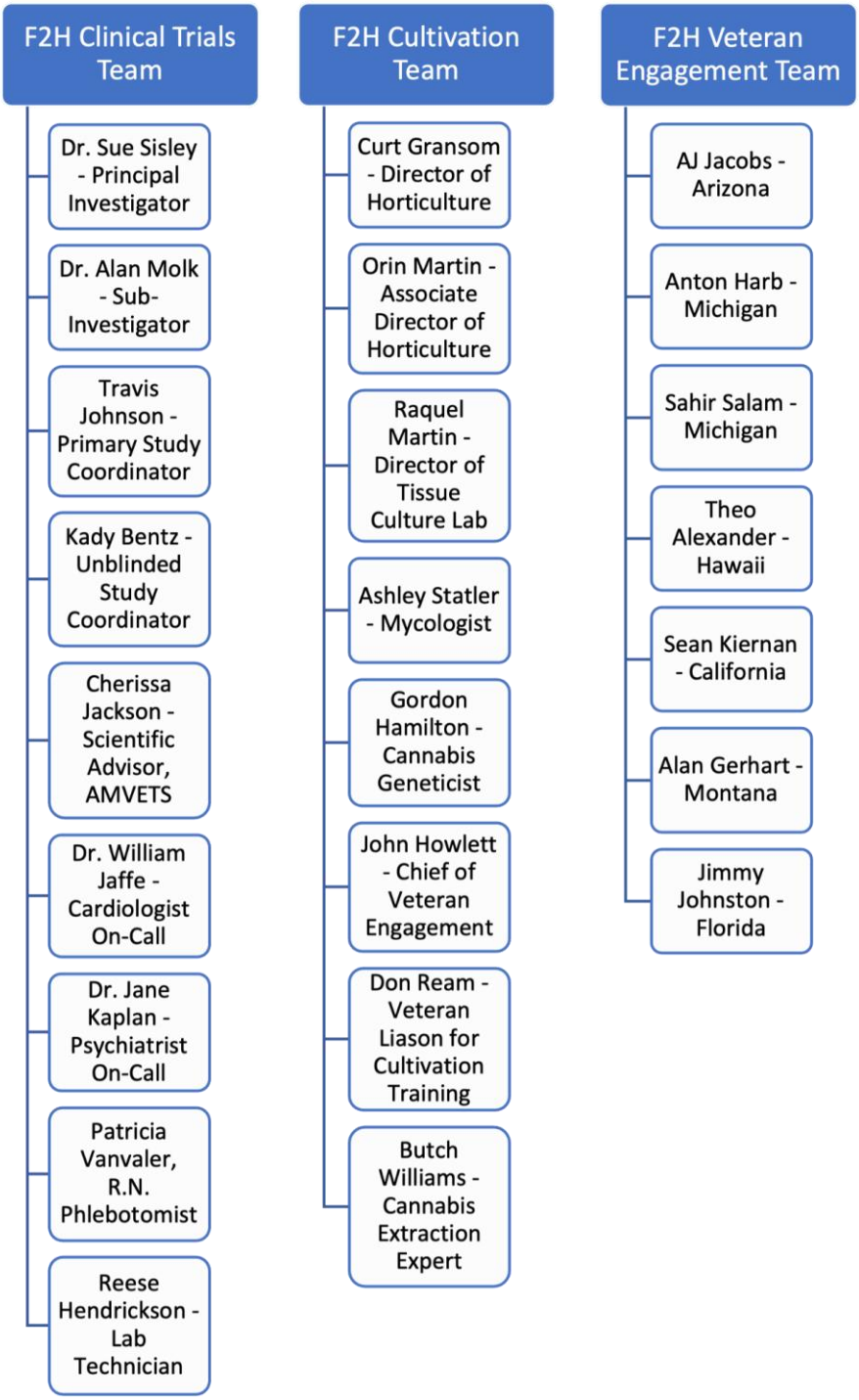
Kevin Cischke, FNP Co-Investigator:
Kevin Cischke completed his MSN with honors in 2018 as a Family Nurse Practitioner at Chamberlain College of Nursing in Addison, Illinois. Cischke currently works at the John D. Dingell VAMC, Detroit, MI, as the Pain Management, Opioid Safety and Prescription Drug Monitoring Program Coordinator (PMOP - Coordinator). In the past, he has served as a Specialty Services Care/Case Program Coordinator and as a COVID-19 Relief Nurse Practitioner at the John D. Dingell VAMC, Detroit, MI, and as a Nurse Practitioner at Prognify Urgent Care in Ann Arbor Michigan. Cischke also worked as an Emergency Room Registered Nurse and as Medical and Surgical Trauma Intensive Care Unit Registered Nurse at Mercy St. Vincent Medical Center Toledo, OH; as Emergency Room Registered Nurse at Mercy Sylvania Medical Center, OH; and as Urgent Care Nurse Practitioner at Best Urgent Care Taylor, MI, and Great Lakes Urgent Care Perrysburg, OH. Kevin Cischke has extensive clinical experience in the emergency department, intensive care, and urgent care setting, as well as advanced knowledge of local, state, and federal nursing laws and scope of practice and complex patient illnesses and disease processes including PCOS, hypothyroid, irritable bowel syndromes.

Brian Kolender, M.D. Co-Investigator:
Dr. Brian Kolender graduated from Wayne State University School of Medicine in Detroit, MI, in 1992 and completed his residency at Rush Presbyterian St. Luke's Medical Center in Chicago, IL, from 1992 to 1995. Kolender worked in a traditional internal medicine practice from 1995 to 2010, then in his traditional solo internal medicine practice from 2010 to 2014, and then moved to an MDVIP-affiliated practice until 2020. He now works at Sante By Kolender in the areas of heart attack and stroke prevention and longevity, and at Healthspan Consulting in the areas of cardiovascular risk reduction and preventive medicine consulting.

Sruthi Kondur, M.D Co-Investigator

Dr. Kondur graduated from the Gandhi Medical College Secunderabad in 2003 and specialized in Anesthesiologist and Pain Medicine. She is Director of the University Health Center Pain Clinic and Clinical Assistant Professor at Wayne State University in Detroit, MI. She is a member of the American Society of Anesthesiologists, American Academy of Pain Medicine, American Society of Interventional Pain Physicians and of Michigan Society of Anesthesiologists. As assistant professor Dr. Kondur is responsible for the close supervision of Anesthesiology Residents and Pain medicine fellows with a considerable attention to procedures, treatment guideline adherence, cost-effective care instruction and care plan assessment. She has refereed at local and national meetings about her pain research.

F2H Members - Organizational Chart



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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 canceled 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 the 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, referring 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 organization F2H, with support from its affiliate SRI. The budget provided in Attachment A does not include matching, leveraged, cost share or any other type of supplemental funds. F2H ensures that it prioritizes and negotiates for the maintenance of the lowest cost possible for all budget items and contracted services, unless otherwise specified. The budget describes a sponsored clinical trial that is planned as a 42-month project which includes: pre-screening of 4,000 potential veterans for study eligibility, formal phone-call screening of 1,200 eligible veteran participants, formal in-lab screening of 600 eligible participants, and ultimately enrolling 300 veterans for participation in this study investigating inhaled cannabis flower for chronic pain indications. The timeline, number of veterans screened, and number of study participants are subject to change. Upon commencement of this study, an estimated 6 months will involve start-up and preparatory activities ensuring extensive training of personnel, supply acquisition, preparation of information systems, and compliance with GCP requirements for clinical trial sites and staff. The clinical trial staff training will begin with an in-person Investigator Meeting planned for January 2023. The CRO will initiate and open study sites for screening by February 2023. Following the Last Patient Last Visit (anticipated in January 2024), the database will be locked and data analyzed for publications and the Final Clinical Study Report for the U.S. FDA in 2025.

Administrative Personnel (Grant Administrator)

Line 4 - Administrative Personnel

Administrative Assistant will assist the Project Manager to oversee the administrative tasks associated with tracking the grant including study costs and expenses.

VMR Program Staff

Line 27 - Dr. Sue Sisley MD

Principal Investigator of Site 1 in Arizona. As the sponsor, Dr. Sisley will assist with the overall management of the VMR program with the assistance of the Project Manager and Administrative Assistant.

At the site level she will hire and supervise local research staff for the project, recruit and track research participants, oversee quality control including protocol fidelity and data accuracy for research conducted at Site 1 site. Dr. Sisley will oversee the implementation of procedures in compliance with DEA regulations. She will devote 30% effort, or 12 hours per week, to this clinical trial throughout the 42 month project period.

VMR Personnel Program Staff

Line 37 -Project Manager

An experienced Project Manager will be hired to oversee the VMR program, at a salary of $100,000 per year. She/He will devote 100 % effort, or 40 hours per week, to this clinical trial throughout the 42 month project period.

VMR Supplies, Material, and Equipment

Line 53 - Cannabis Drug Cost

High THC cannabis (investigational drug) will be supplied by SRI at a zero-profit margin, with grant funds covering manufacturing and production. It costs SRI $1684.54 to produce 1 pound of botanical cannabis

flower. 37 pounds of high THC cannabis are required to meet the allotment of 2 grams per day, for 150 participants, over the course of the study.

Line 54 - Placebo Cannabis Drug Cost

Placebo cannabis will be supplied by SRI at a zero-profit margin, with grant funds covering manufacture, production, and extraction. It costs SRI $1684.54 to produce 1 pound of botanical cannabis flower. Additional extraction processing to remove THC, terpenes, and CBD is required to obtain 37 pounds of placebo cannabis needed for the study. **These fees total $49,000.**

Line 55 - Site 1 - Site Set-Up Fee

A one-time study Site Set-Up Fee of $50,000 per site for study specific direct costs related to supplies, equipment and infrastructure. This expense is to ensure sites are set up and ready to conduct the clinical trial and includes but not limited to ensuring the site is set up to store and maintain cannabis IP including required storage e.g. safe, have the appropriate licensing, locked room, insurance, ventilation for the dosing of inhaled flower and extensive site training on medical cannabis, use of vaporizer, dosing treatment protocols etc. We will only use the amount needed to ensure that the research site has the supplies, equipment and infrastructure costs approved to ensure that they can appropriately conduct the study.

Line 56 - Site 2 - Site Set-Up Fee

A one-time study Site Set-Up Fee of $50,000 per site for study specific direct costs related to supplies, equipment and infrastructure. This expense is to ensure sites are set up and ready to conduct the clinical trial and includes but not limited to ensuring the site is set up to store and maintain cannabis IP including required storage e.g. safe, have the appropriate licensing, locked room, insurance, ventilation for the dosing of inhaled flower and extensive site training on medical cannabis, use of vaporizer, dosing treatment protocols etc. We will only use the amount needed to ensure that the research site has the supplies, equipment and infrastructure costs approved to ensure that they can appropriately conduct the study.

Line 57 - Site 3 - Site Setup-Up Fee

A one-time study Site Set-Up Fee of $50,000 per site for study specific direct costs related to supplies, equipment and infrastructure. This expense is to ensure sites are set up and ready to conduct the clinical trial and includes but not limited to ensuring the site is set up to store and maintain cannabis IP including required storage e.g. safe, have the appropriate licensing, locked room, insurance, ventilation for the dosing of inhaled flower and extensive site training on medical cannabis, use of vaporizer, dosing treatment protocols etc. We will only use the amount needed to ensure that the research site has the supplies, equipment and infrastructure costs approved to ensure that they can appropriately conduct the study.

Line 58 - Participant Payments and Remuneration

There will be 300 participants completing the proposed study. Participants will be compensated for their time as follows:

$50.00 for screening visit (we anticipate that we will need to screen 600 participants to enroll 300 participants)=**$ 30,000**

$50.00 for baseline, treatment and end of study visit for a total of 4 visits (300 participants)=**$ 60,000**

Clincard costs per card is Physical card fees: 600 x 5.00/card = **$3,000**

Load fees: 600 x 1 session x $1.50/load = **$ 900**

Load fees: 300 X 4 sessions x $1.50/load= **$ 1,800**

Total: **$ 95,700**

Line 59 - Vaporizers (Brand is TBD)

Each study participant will be given a vaporizer for inhalation of the study drug or placebo, for the

duration of the study. Vaporizer estimation (with appropriate accessories) is approx. $500. **Total: $155,000** (accounts for 300 vaporizers and accessories with 10 additional vaporizers to account for training purposes at each site)

Line 61 - Marketing

In order to recruit veteran participants for this study, marketing and outreach strategies are required to help facilitate further reach including diverse populations. Veterans' Groups, Veterans' Networks, Veteran Service Organizations, partnerships with the VA, and private clinician offices will be targeted. The cost per year of such marketing strategies is $50,000 per year for a total of **$175,000.** This will include print ads focused in Michigan primarily and also veteran focused including magazines and/or digital media marketing focused on veteran populations. This includes a micro website and utilizing companies such as Trialfacts and/or Auto Recruitment that would facilitate online pre-screening activities and therefore limiting site staffing costs and work burden as this study could take up to 4000 phone screens, with 1,200 phone-call screening to enroll 300 participants into the clinical trial.

Line 65 - WCG Analgesic Solutions, Inc. – Placebo Response Training

WCG Analgesic Solutions, Inc., is the sole provider on the market for Placebo Response Reduction Training. A competitive bidding process is therefore not possible. The estimated quote for these services is $280,820. As a sizable placebo response was previously detected in similar clinical trials, this expense appears to be necessary.

Line 66 - Contract Research Organization

The process of receiving proposals from Contract Research Organizations is underway. Previous studies of similar scope and size have resulted in bids outlining costs of $3,500,000. This item may be updated after grant award to reflect a lower CRO fee, resulting in fewer grant dollars spent on this service.

Line 67 - Study Site 1 - Phoenix, Arizona

F2H put together a budget of $1,700,000 for the conduct of the trial as one of 3 clinical trial sites, enrolling 100 veterans with chronic pain in this trial.

Line 68 - Study Site 2, Detroit, Michigan

Dr. Abboud put together a budget of $1,600,000 for the conduct of the trial as one of 3 clinical trial sites, enrolling 100 veterans with chronic pain in this trial.

Line 69 - Study Site 3, TBD

A third clinical trial site, location TBD, will follow the budget of Study Site 2 with a budget of $1,600,000 for the conduct of the trial as one of 3 clinical trial sites, enrolling 100 veterans with chronic pain in this trial.

Line 70 - Drug Screening

Drug screening tests are required to determine participant eligibility. The cost for each test is $15. The sponsor anticipates performing these tests for 900 participants.

Line 71 - Pregnancy Tests

Pregnancy tests are required for female study participants, to determine eligibility to participate in the study. For female participants who have the potential to become pregnant during the course of the study, repeat pregnancy tests will be required at in-person visits. Each pregnancy test costs $23. The sponsor anticipates performing 75 pregnancy tests across both sites.

Line 72 - Lab Screening Tests

Lab screening tests for CBC liver function, urinalysis, and electrolyte levels are required during the in-person participant screening visit. The cost for these tests is $100. The sponsor anticipates performing these tests for 600 participants.

Line 76 - Ethics Submission $ 12,000 per site.

VMR Travel Expenses

Line 79 - Investigator Meeting Transportation

Transportation to and from Investigator Meetings for Principal Investigators, clinical trial staff, and key CRO personnel across all 3 study sites will total $20,000.

Line 80 - Investigator Meeting Meals

During Investigator Meetings, meals for Principal Investigators, clinical trial staff, and key CRO personnel across all 3 study sites will total $2,500.

Line 81 - Investigator Meetings Lodging

Lodging for Principal Investigators, clinical trial staff, and key CRO personnel across all three study sites will be required during Investigator Meetings, and will cost $25,000.

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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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Please see the attached Letters of Support from Veterans' Groups

Balanced Veterans Network
501c3 Nonprofit Organization
776 Hill Road
Philadelphia, PA 19128
TEL (267) 989-9156
info@balancedveterans.com
https://www.bvn.vet

Dear Michigan Marijuana Regulatory Agency,

I am writing in support of the proposed veterans Cannabis research from the Field to Healed Foundation in coordination with Dr. Sue Sisley.

We are confident that F2H and Dr. Sisley will be able to properly execute this proposed FDA trial examining the impact of inhaled dry cannabis flower for treating chronic pain in military veterans, and also measuring potential opioid reduction.

We are familiar with the cannabis strains that have been identified for this trial. These strains were specifically identified and selected utilizing direct feedback from veterans who utilize cannabis. The quality of this cannabis more closely reflects the robust sun-grown mid/high-THC Cannabis Flower that veterans are typically seeking versus previous, government chosen strains.

Balanced Veterans Network (BVN) is a 501(c)3 non-profit focused on initiatives tailored around education and advocacy for alternative, life-saving therapies for veterans. These initiatives include cannabis, mental wellness, movement, project triangle, and community. BVN has members located across the United States and provides an online space for veterans to connect, attend weekly wellness classes, and obtain important education regarding cannabis; as well as other holistic wellness modalities. Since BVNs inception in 2017, BVN has provided education to approximately 350,000 veterans by means of panels, podcasts, magazine articles, and community events. BVN is an all-inclusive community who accepts veterans from any era. While our initiatives speak for themselves, our ultimate mission is to save veterans lives. One of the most common stories many of our members share is how the incorporation of cannabis and elimination of toxic pharmaceuticals has allowed veterans the ability to live a healthier, higher quality life.

In addition to BVN's and other veteran organization's support of this trial, groundbreaking support from the Detroit Veterans Administration (VA) proves that de-stigmatization of cannabis for veterans is happening. However, it can only continue to evolve with proper trials and research, such as this.

We wholeheartedly believe that this objective research trial will continue to pave the way for alternative-life saving options for veterans.

Sincerely,

Jennifer Baxter 

Executive leadership team, Balanced Veterans Network

DATE: May 25, 2022

TO: Michigan Cannabis Regulatory Agency (CRA)

FROM: Anton Harb Jr.
Veteran Advisor
Hero Project USA

SUBJECT: Letter of Support RE: Dr. Sue Sisley, Veteran PTSD Cannabis Research Grant

To whom it may concern,

I am writing in support of the proposed veterans Cannabis research from the Field to Healed Foundation (F2H).

F2H has deep ties in the veteran community nationally and has been at the forefront of some of the most important veterans cannabis (and recently adding psychedelics) research in the US.

We are confident that F2H/Dr. Sisley will be able to execute this proposed FDA randomized controlled trial examining the safety/efficacy of inhaled dry cannabis flower for treating chronic pain/PTSD in military veterans, and also measuring potential opioid reduction.

We are familiar with Dr. Sisley's Cannabis Flower that F2H is cultivating under a DEA schedule 1 manufacturing license. This is consistent with the quality of cannabis flower that is used by veterans in the real world. Dr. Sisley fought the federal government for many years in order to obtain this DEA cultivation license so she could implement veterans research that more closely reflected the robust sun-grown mid/high-THC Cannabis Flower that veterans are typically seeking. So, we believe this study can level the playing field and give cannabis a fair chance at demonstrating better outcomes as a potential medicine for our veteran community.

Hero Project USA (HP) is a registered 501c3 nonprofit organization based in the State of Michigan (MI). Since launching in 2021, HP has been on the front lines of advocating for a veteran's right to access and use medical cannabis as an alternative form of therapy to ease the symptoms of chronic pain, Traumatic Brain Injury (TBI) and Post Traumatic Stress Disorder (PTSD). Unfortunately, many veterans are still subjected to myriad dangerous pharmaceutical cocktails, which result in unnecessary side effects and even worse, veteran deaths. HP believes medical cannabis research is paramount to assist in shaping sensible policy at the Federal level. Dr. Sisley has proven her research methods are above reproach and stand to create accurate data which will hopefully lead to positive impact in veterans' lives.

In order for any clinical trial to be successful, the research team must have robust access to the population of individuals they are researching. HP has formed strategic partnerships with VetLife and Canna Social Equity Fund (CSEF) to assist Dr. Sisley and her team obtain access to a large portion of the MI veteran population. VetLife, a 501c3 organization based in MI, specializes in bringing large groups of veterans together through resource fairs and other social activities. CSEF is a nonprofit organization aimed at assisting MI's cannabis industry in meeting their social equity requirements as outlined in MI's cannabis laws. HP, CSEF and VetLife aim to leverage our resources and other platforms established in the veteran and cannabis community to provide Dr. Sisley with access to as many veterans as we can reach. In order for this study to be successful, thousands of MI veterans will need to be screened. We believe we can be a sustainable resource for Dr. Sisley to screen and research as many veterans as her research will allow.

In closing, as a 100% service-connected disabled veteran, I have survived cancer, suicide and combat. I fully support the work Dr. Sisley has embarked upon and would feel honored to support this extremely important endeavor. If there are any further questions, please feel free to reach out any time.

Sincerely,

Anton Harb Jr.
Hero Project USA
716-553-6935

DocuSigned by:
Duane Siefert
2F08617E07EB49D...

5/30/2022

322 4th Ave E, Olympia WA 98501-1107 | (253) 777-5857
Twenty22Many-Olympia.org
A 501(c)3 Corporation - EIN# 81-3698580

Dear MRA,

May 29, 2022

We are writing in support of the RFP proposal for Veterans Cannabis research from the Field to Healed Foundation.

I have been leading the charge for veterans access to medical cannabis in Washington State & Michigan for over a decade. I'm the founder of Twenty22Many. We have a strong chapter in Michigan and we are eager to help with recruitment of study subjects. My organization is directly responsible for getting PTSD added to the list of qualifying conditions for medical cannabis use in over 10 states. Now because of our efforts veterans can use medical cannabis safely and effectively without fear of losing their benefits. I've been all over the world advocating for Vets medical cannabis access for Veterans from Washington DC to Oklahoma to California to the United Nations.

I am confident that F2H/Dr. Sisley will be able to execute this proposed FDA randomized controlled trial examining the safety/efficacy of inhaled dry cannabis flower for treating chronic pain in military veterans, and also measuring potential opioid reduction.
We are familiar with Dr. Sisley's Cannabis Flower that F2H is cultivating under DEA schedule 1 manufacturing license. This is consistent with the quality of cannabis flower that is used by veterans in the real world. Dr. Sisley fought the federal government for many years in order to obtain this DEA cultivation license so she could implement veterans research that more closely reflected the robust sun-grown mid/high-THC Cannabis Flower that veterans are typically seeking. So we believe this

DocuSigned by:
Duane Siefert
2F0B617E07EB49D...

5/30/2022

322 4th Ave E, Olympia WA 98501-1107 | (253) 777-5857
Twenty22Many-Olympia.org
A 501(c)3 Corporation - EIN# 81-3698580

study can level the playing field and give cannabis a fair chance at demonstrating better outcomes as a potential medicine for our veteran community.

Twenty22Many fully supports Veterans accessing medicinal cannabis for the treatment of chronic pain and PTSD. We are in favor of Cannabis research as it relates to PTSD treatment for Veterans. We supported the "Safe Harbour Act" that was passed in the House of Representatives this past Spring. Twenty22Many understands the importance of research and welcomes the opportunity to support efforts exploring the efficacy of cannabis to save the lives of our brave warriors. 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.

Dr. Sisley marched with Twenty22Many at the Washington State Capital (Olympia) nearly 10 years ago to show her unwavering support for veterans access to medical cannabis and to bring about the end of the Veterans Suicide Epidemic. I can't think of a more qualified or selfless doctor or human being to lead this research.

Sincerely & Respectfully,

Patrick Seifert
Founder Twenty22Many
Marine Corp Veteran

HEROIC
HEARTS
PROJECT

Dear MRA,

I am writing in support of the proposed veterans Cannabis research from the Field to Healed Foundation. F2H has deep ties in the veterans community nationally and has been at the forefront of some of the most important veterans cannabis/(recently adding psychedelics) research in the US.

I am confident that Dr. Sisley will be able to execute this proposed FDA randomized controlled trial examining the safety/efficacy of inhaled dry cannabis flower for treating chronic pain in military veterans, and also measuring potential opioid reduction. I am familiar with Dr. Sisley's Cannabis Flower that she is cultivating under DEA schedule 1 manufacturing license. This is consistent with the quality of cannabis flower that is used by veterans in the real world. Dr. Sisley fought the federal government for many years in order to obtain this DEA cultivation license so she could implement veterans research that more closely reflected the robust sun-grown mid/high-THC Cannabis Flower that veterans are typically seeking. So I believe this study can level the playing field and give cannabis a fair chance at demonstrating better outcomes as a potential medicine for our veteran community.

I am an Army Ranger veteran with 3 combat deployments to Afghanistan. I am writing to you today as both a military veteran and a US citizen. As a veteran, I represent the voice of a community that is suffering through an unprecedented mental health crisis. Therapies based on similar medicinal plants saved my life as well as the lives of countless other veterans. Among the veteran population, rates of Post Traumatic Stress Disorder, depression, and suicide have soared. Since the start of the Global War on Terrorism, more veterans have died as a result of suicide than in combat by more than a factor of 20. Veterans are also four times more likely to have suffered from opioid addiction as a direct result of negligent pain management programs. Despite over $80 billion dollars of funding, the Department of Veteran Affairs (VA) has not been able to find any real solutions to this epidemic.

Naturally occurring substances like cannabis have been shown to help veterans.struggling with chronic pain and anxiety. It has also allowed countless veterans to come off or reduce medication intake, especially opioids. Unfortunately, due to outdated drug policy laws, it has been nearly impossible to study life-saving plants like cannabis for the past 50 years. Dr. Sue Sisley has tirelessly worked in spite of these barriers because this nation's veterans deserve more tools to help them regain a normal life.

HEROIC
HEARTS
PROJECT

This research is absolutely necessary and Dr. Sue Sisley is the most qualified to conduct it. I strongly urge you to support the proposed cannabis research so that we can start giving veterans a fighting chance.

Sincerely,
Jesse Gould

Executive Director
Heroic Hearts Project

SERVING WITH PRIDE

AMVETS, which is also known as *American Veterans*, is the most inclusive Congressionally-chartered veterans service organization open to representing the interests of 20 million veterans and their families. We are veterans serving veterans since 1944. Founded in 1944 and chartered by an act of Congress, the AMVETS organization has more than 250,000 members nationwide. AMVETS exists to enhance the quality of life for all veterans, their families and survivors. Membership in AMVETS is open to anyone who honorably served or is currently serving in the U.S. Armed Forces, including the National Guard and Reserves. Our award winning **HEAL Program** assist Veterans through Healthcare, Evaluation, Advocacy and Legislation. Our program provides resources and options for Veterans interested in a holistic approach for treatment of PTSD, MST, Opioid and Substance Abuse, and Suicidal Ideation.

AMVETS has a resolution (Resolution 19-13) that's in support of Veteran accessing medicinal cannabis for the treatment of chronic pain and PTSD. We are in favor of Cannabis research as it relates to PTSD treatment for Veterans. We supported the "Safe Harbour Act" that was passed in the House of Representatives this past Spring. The organization understands the importance of research and welcomes the opportunity to support efforts exploring the efficacy of cannabis to save the lives of our brave warriors. 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.

I believe undoubtably that with AMVETS help, Dr. Sisley will be successful. The HEAL Program is here to assist Dr. Sisley with Veteran recruitment efforts as she conducts a new FDA phase 2 trial examining inhaled cannabis.

5/30/2022

Sincerely, DocuSigned by: 1114D96F9959484...

Cherissa Jackson

Chief Medical Executive AMVETS

AMVETS

NATIONAL
HEADQUARTERS
4647 Forbes Boulevard
Lanham, Maryland
20706-4380
TELEPHONE: 301-459-9600
FAX: 301-459-7924
E-MAIL: amvets@amvets.org

Kevin Cischke, NP

May 29, y

Marijuana Regulatory Agency (MRA), Joint Evaluation Committee (JEC)

2022 Veteran Marijuana Research (VMR) Grant Program

Dear MRA/JEC,

I'm writing to express my support for this RFP and my enthusiasm about working with this proposed FDA approved controlled clinical trial looking at inhaled cannabis for military veterans with pain. My involvement with this trial will be informed by my role on the Detroit VA Pain Committee, but I will be functioning independently and participating on my personal time outside of my VA work hours.

In my attached CV, you can see I have extensive experience managing military veterans with chronic pain. I have always been curious about the potential for cannabis to treat pain and I've heard many veterans report benefits from the use of inhaled whole plant cannabis flower. This is why I am eager to serve as a co-investigator on this upcoming research, because this group Field To Healed Foundation has a long track record of conducting FDA trials on cannabis and they know how to navigate the regulatory hurdles associated with studying schedule 1 drugs. Feel free to contact me at the number below if you have further questions, or at my personal email: durufle@gmail.com

Sincerely yours,

Kevin Cischke

Michigan-licensed Family Nurse Practitioner

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END APPLICANT RESPONSE

V-J Certificate of Approval

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:  5/31/2022

Authorized Signatory and Title Date

Name of Organization

ATTACHMENT A: SAMPLE VMR BUDGET
Submission Date: June 1, 2022
Selected Applicant's Grant Number: _____

Below is a sample budget in the required format for this RFP and the resulting grant agreement(s). All numbers are fictitious and must be removed and replaced with actual proposed budget amounts prior to submission of the proposal.

Line Item	Budget Category	TOTAL
1	**Administrative Expenses**	
2	**Administrative Personnel (Grant Administration Staff)**	
3	*Salary*	
4	Administrative Assistant (30,000.00 per year)	105,000.00
5		
6	**Total Salary**	105,000.00
7	*Fringe Benefits*	
8		
9		
10	**Total Fringe Benefits**	NAP
11	***Total Administrative Personnel***	105,000.00
12	**Administrative Supplies, Materials, and Equipment**	
13	General Office Supplies	-
14	***Total Administrative Supplies, Materials, & Equipment***	
15	**Administrative Contractual Services**	
16	Does not apply	
17	***Total Administrative Contractual Services***	
18	**Administrative Travel (Grant Administration Staff)**	
19	Mileage	$20,000
20	Meals	$25,000
21	Lodging	$25,000
22	***Total Administrative Travel***	
23	**Total Administrative Expenses**	**175,000.00**
24	**VMR Program Expenses**	
25	**VMR Program Staff**	
26	*Salary*	
27	Dr. Sue Sisley, Principal Investigator (140,000 per year)	$490,000.00
28		
29	**Total Salary**	490,000.00
30	*Fringe Benefits*	
31	Employee 2 (Coordinating Principal Investigator)	TBD

32	Employee 3 (Chair, Data Monitoring Board)	TBD
33	**Total Fringe Benefits**	
34	***Total VMR Program Staff***	
35	**VMR Personnel Program Staff**	
36	*Salary*	
37	Project Manager (100,000 per year)	$350,000.00
46	**Total Salary**	$350,000.00
47	*Fringe Benefits*	
48	Costs TBD 2 (Job Title)	
49	Costs TBD 3 (Job Title)	
50	**Total Fringe Benefits**	
51	***Total VMR Personnel Program Staff***	**840,000.00**
52	**VMR Supplies, Materials, & Equipment**	
53	Cannabis Investigational Product Cost	$62,395
54	Placebo Cannabis Investigational Product Cost	$111,395
55	Site 1 - Site Set-Up Fee	$50,000
56	Site 2 - Site Set-Up Fee	$50,000
57	Site 3 - Site Set-Up Fee	$50,000
58	Participant Remuneration	$ 95,700
59	Vaporizers, 1 per Study Participant ($400 per Vaporizer) 120,000	$123,600
61	Marketing (30,000 per year)	$105,000
62		
63	***Total VMR Supplies, Materials, & Equipment***	**648,090.00**
64	**VMR Contractual Services**	
65	WCG Analgesic Solutions, Inc. – Placebo Response Reduction Training	$280,820
66	CRO	$3,500,000
67	Study Site 1 - Phoenix, Arizona	$1,700,000
68	Study Site 2 - Detroit, Michigan	$1,600,000
69	Study Site 3 - TBD, Western Michigan Site	$1,600,000
70	Drug Screening	$13,500
71	Pregnancy Tests	$1,725
72	Lab Screening Tests	$60,000
73	Ethics Submission, 3 Sites	$36,000
76		
77	***Total VMR Contractual Services***	**8,792,045.00**
78	**VMR Travel (VMR Staff)**	
79	Investigator Meeting Transportation	$20,000
80	Investigator Meeting Meals	$2,500
81	Investigator Meetings Lodging	$25,000

82	***Total VMR Travel***	**47,500.00**
83	**VMR Other**	
84	Does not apply	$ -
85	***Total EAP Other***	$ -
86	**Total VMR Program Expenses**	**$840,000.00**
87	**Total Direct Cost**	**$ $9,854,545.00**
88	*Indirect Cost (0.10)*	$985, 454.00
89	**TOTAL PROJECT COST**	**$10,839,999.50**