



GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
CANNABIS REGULATORY AGENCY

MARLON I BROWN
DIRECTOR

BRIAN HANNA
EXECUTIVE DIRECTOR

GRANT AMENDMENT #1

Effective Date July 30, 2024

Grant No: VMR202102

Grantee: Multidisciplinary Association for Psychedelic Studies (MAPS)

The Multidisciplinary Association for Psychedelic Studies (MAPS) has requested to amend their budget and extend their grant period until December 31, 2027. The amended budget will align with the new budget that decreases cost allocations in personnel and increases cost allocations in contractual services that were approved in the initial grant award. No new contracts are being bid or secured as a result of this amendment. An extension is being requested as the grant is set to expire in July 2024. The purpose of this amendment is to adjust funds from the categories listed below. All other terms and conditions of the grant agreement shall remain unchanged and in effect. The amended grant amount is equal to the original grant amount, with no change in overall funding.

Grantee's budget is amended as follows:

Budget Category	Original	Amended
<i>Administrative Expenses</i>		
Administrative Personnel	\$1,006,846	\$ 357,894
Administrative Supplies, Materials, and Equipment	\$173,068	\$ 173,068
Administrative Contractual Services	\$0	\$ 0
Administrative Travel	\$0	\$ 0
Indirect Administrative Expenses	\$0	\$ 648,952
Administrative Expenses TOTAL	\$1,179,914	\$ 1,179,914
<i>VMR Program Expenses</i>		
VMR Program Staff	\$2,127,337	\$ 916,263
VMR Supplies, Materials, and Equipment	\$1,031,231	\$ 394,064
VMR Contractual Services	\$7,811,143	\$10,464,809
VMR Travel	\$80,625	\$ 24,000
VMR Other	\$748,800	\$ 0
Direct Assistance	\$0	\$ 0
VMR Program Expenses TOTAL	\$11,799,137	\$11,799,137
Total Direct Cost	\$11,799,137	\$11,799,137
Indirect Cost	\$1,179,914	\$1,179,914
Total Project Cost	\$12,979,050	\$12,979,050

E-SIGNED by Laura Kwiecien
on 2024-08-08 16:38:11 EDT

Laura Kwiecien, Procurement Director
Procurement & Administration Division
Bureau of Finance and Administrative Services
Department of Licensing and Regulatory Affairs
State of Michigan

Date

E-SIGNED by Kris Lotlikar
on 2024-08-21 14:04:08 EDT

Kris Lotlikar, Executive Director
Multidisciplinary Association for Psychedelic
Studies (MAPS)

Date

VETERAN MARIJUANA RESEARCH GRANT PROGRAM BUDGET AMENDMENT

Effective Date: 6/1/2024

Proposed Grant Period: August 16, 2021 through December 31, 2027

Grantee: MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES (MAPS)

Grant No: VMR202102

Explanation for budget change and explanation of each line item being amended:

An extension is being requested as the grant is set to expire in July 2024. The new request would set the grant to expire in December 31, 2027.

The applicant for this grant is the non-profit MAPS. The budget provided in Attachment A does not include matching, leveraged, cost share or any other type of supplemental funds. The applicant has negotiated the majority of the costs for the lowest cost possible, unless otherwise specified below. Due to funding constraints of the VMR program that were conveyed to MAPS on July 28, 2021, the budget included herein was amended to \$12,979,050. The original budget included enrollment and treatment of 360 veterans with all associated costs at 6 clinical trial sites and funds for contingency. The amended budget includes enrollment of complete treatment of 320 veterans at 3 clinical trial sites with inhaled botanical cannabis. Both the time and the numbers of veterans are subject to change, as additional supplies for 40 veterans who start but do not complete the trial are still included within the budget in the case of dropouts from the trial.

The amended budget does not otherwise include built in contingencies. The amended budget describes a sponsored clinical trial that is planned as a 35-month project. Possible delays may arise due to the ongoing COVID-19 global health pandemic. The first several years of this project have included ongoing regulatory challenges due to the unprecedented nature of this research. Following FDA-approval, we anticipate a 6 month start-up period dedicated to preparation of personnel, supplies, information systems, and activation of clinical trial sites. Sites will be initiated by the Contract Research Organization and opened for screening by February 2025. The Last Patient Last Visit is anticipated to occur prior to September 2027 and will be followed by database lock and data analysis for publications and the Final Clinical Study Report for the U.S. FDA in 2027.

Administrative Costs enumerated below are capped at the 10% de minimis Indirect rate stipulated per the funding guidelines, as such no indirect costs are claimed for the grant:

Salary does not include sick pay, vacation pay, holiday pay, bonuses, overtime, tuition reimbursement/remission, vehicle allowance, seminars, conferences, meetings, subscriptions, dues, and memberships. In the past, fringe rates were included inconsistently and never surpassed 28% of the adjusted salary costs based on the grant period. Henceforth, fringe rates are calculated as 16% of the adjusted salary costs based on the grant period. Fringe rates include health, dental, and optical insurance, employer-paid Social Security and Medicare tax, Federal unemployment tax, and other miscellaneous fringe benefits (life insurance, long- and short-term disability insurance, worker's compensation, and retirement program contributions up to 4%).

[Current & projected administrative personnel of MAPS are listed below.](#)

4, 21

Line

Rick Doblin, MAPS Executive Director

Will assure the appropriate use of grant funds through setting financial controls, organizational strategy, and resource allocations to the study organization-wide throughout the grant period. Doblin was not compensated from the grant in 2021 or 2022. In 2023, Doblin was compensated \$20,198.82 in salary and \$2,442.60 in fringe. For the remaining

grant term, it is projected that Doblin will be compensated an annual salary of \$25,000.00 and \$4,000.00 in fringe.

5, 22 Erin Tasman, MAPS Vice President of Finance & Philanthropy

Will provide oversight of grant funds and function as the grant authorized negotiator throughout the grant period. Tasman was not compensated from the grant in 2021 or 2022. In 2023, Tasman was compensated \$6,183.18 in salary and \$809.75 in fringe. For the remaining grant term, it is projected that Tasman will be compensated an annual salary of \$7,000.00 and \$ 1,120.00 in fringe.

6, 23 Fede Menepace, MAPS Deputy Director

Will assure the appropriate use of grant funds through setting financial controls, organizational strategy, and resource allocations to the study organization-wide throughout the grant period. Menepace was not compensated from the grant in 2021 or 2022. In 2023, Menepace was compensated \$7,225.15 in salary and \$801.38 in fringe. For the remaining grant term, it is projected that Menepace will be compensated an annual salary of \$8,000.00 and \$1,280.00 in fringe.

7, 24 Matt Clark, MAPS Associate Director of Grants

Will direct budget development, management, and reporting throughout the grant period. Clark was not compensated from the grant in 2021 or 2022. In 2023, Clark was compensated \$8,660.36 in salary and \$1,641.59 in fringe. It is projected that Clark will be compensated an annual salary of \$5,000.00 and \$800.00 in fringe in 2024, and an annual salary of \$1,500.00 and \$240.00 in fringe in the remaining grant years.

8, 25 Ryan Barnes, MAPS Associate Director of Finance

Will execute budget management and reimbursement and support budget reporting throughout the grant period. Barnes was not compensated from the grant in 2021 or 2022. In 2023, Barnes was compensated \$504.50 in salary and \$83.75 in fringe. For the remaining grant term, it is projected that Barnes will be compensated an annual salary of \$1,500.00 and \$240.00 in fringe.

9, 26 Emily Williams, MAPS Senior Accountant

Will support expense reimbursement and budget reporting throughout the grant period. Williams was not compensated from the grant in 2021 or 2022. In 2023, Williams was compensated \$105.85 in salary and \$14.12 in fringe. For the remaining grant term, it is projected that Williams will be compensated an salary of \$1,000.00 and \$160.00 in fringe.

10, 27 Jennifer Ellis, MAPS Vice President of People & Operations

Will provide oversight of personnel resource allocation and support budget reporting related to personnel expenses throughout the grant period. Ellis was not compensated from the grant in 2021 or 2022. In 2023, Ellis was compensated \$535.57 in salary and \$75.38 in fringe. For the remaining grant term, it is projected that Ellis will be compensated an annual salary of \$1,000.00 and \$160.00 in fringe.

11, 28 Open Position, MAPS People Operations Manager

Will support accurate reporting of personnel expenses throughout the grant period. It is projected that this role will be compensated an annual salary of \$8,500.00 and \$1,360.00 in fringe in 2024, and an annual salary of \$12,000 and \$1,920.00 in fringe in the remaining grant years.

12, 29 Betty Aldworth, MAPS Director of Communications & Post-Prohibition Strategy

Will provide communications expertise and support the public dissemination of news related to the study, including making regulatory documentation accessible to the public. Aldworth was not compensated from the grant in 2021 or 2022. In 2023, Aldworth was compensated \$389.96 in salary and no fringe For the remaining grant term, it is

projected that Aldworth will be compensated an annual salary of \$1,000.00 and \$160.00 in fringe.

13, 30 Ray Allen, MAPS General Counsel

Will provide legal expertise on all aspects of study conduct, as requested. Allen was not compensated from the grant in 2021 or 2022. In 2023, Allen was compensated \$2,328.84 in salary and \$145.04 in fringe. For the remaining grant term, it is projected that Allen will be compensated an annual salary of \$2,500.00 and \$400.00 in fringe.

14, 31 Allyson Deraps, MAPS Outside Counsel

Will support contract development and maintenance with contracted services throughout the duration of the grant term. Deraps was not compensated from the grant in between 2021-2023. For the remaining grant term, it is projected that Deraps will be compensated an annual salary of \$4,103.40 and no fringe in 2024 and an annual salary of \$5,000.00 and no fringe in 2025.

Former administrative personnel of MAPS and Lykos Therapeutics are listed below.

Line

15, 32 Allison Coker, Lykos Therapeutics Regulatory Affairs Manager

Ensured that all U.S. FDA regulatory communications were efficient, accurate, and timely. In 2021, Coker was compensated \$2,681.50 in salary and no fringe. In 2022, Coker was compensated \$334.60 in salary and no fringe. In 2023, Coker joined MAPS as a contract employee to conduct regulatory strategy on this study as a VMR administrative personnel.

16, 33 Desiree Lopez, MAPS Human Resources Administrator

Supported accurate reporting of personnel expenses throughout the grant period. Lopez was not compensated from the grant in 2021 or 2022. In 2023, Lopez was compensated \$311.52 in salary and \$88.52 in fringe.

17, 34 John Poncini, MAPS Product Engineer

Supported implementation of IT services. Poncini was not compensated from the grant in 2021 or 2022. In 2023, Poncini was compensated \$345.29 in salary and \$70.92 in fringe.

18, 35 Allison Coker, MAPS Program Manager

Manage regulatory strategy, prepare regulatory submissions, maintain vendor relationships, and support grant communications. Coker was compensated a total of \$12,091.91 in salary and no fringe for 3 months labor in 2023 before transitioning to a program personnel role.

Current/ongoing overhead costs are defined below:

39 Information Technology/Information Systems expenses incurred from project commencement to Q4 2023 were billed in 2023 for a total expense of \$33,768.00. IT/IS expenses incurred in Q1 2024 - Q3 2024 were billed in 2024 for a total expense of \$16,892.00. Starting in Q3 2024, IT/IS will be billed/accounted for in the overall indirect project expense allocation.

40 10% Allocation for clinical trial insurance policy premiums for 45 months at a total cost of \$122,408.00.

VMR Program Personnel Costs:

For former and current/ongoing VMR Program personnel, salary that is listed as directly contributing to the budget does not include sick pay, vacation pay, holiday pay, bonuses, overtime, tuition reimbursement/remission, vehicle allowance, seminars, conferences, meetings, subscriptions, dues, and memberships. In the past, fringe rates were included inconsistently and never surpassed 28% of the adjusted salary costs based on the grant period. Henceforth, fringe rates are calculated as 16% of the adjusted salary costs based on the grant period. Fringe rates include health, dental, and optical insurance, employer- paid Social Security and Medicare tax, Federal unemployment tax, and other miscellaneous fringe benefits (life insurance, long- and short-term disability insurance, worker's compensation, and retirement program contributions up to 4%).

Current & projected MAPS program personnel are listed below.

Line

- 51, 72 Allison Coker, MAPS Director of Research
- Responsible for regulatory strategy and program oversight. Coker was paid in 2021 and 2022 as an administrative personnel at Lykos Therapeutics. In 2023, Coker transitioned from Lykos to a MAPS contract employee. Coker was initially compensated as MAPS administrative personnel (see separate entry), before transitioning to program personnel in April 2023. Coker was compensated \$55,256.60 in salary and \$2,390.97 in fringe in 2023 for 9 months of labor. It is projected that Coker will be compensated an annual salary of \$70,000.00 and \$2,800.00 in employment tax in 2024, and an annual salary of \$40,000.00 and \$1,600.00 in employment tax for the remaining grant years. No additional Fringe is included as this is a contract role.
- 52, 73 McKenna Leighton, MAPS Clinical Research Manager
- Will support regulatory submission preparation, quarterly grant reports, managing CRO and other contracted services, designing the CMC supply & distribution process, and general study start-up until a Clinical Program Manager is hired and assigned to manage the study. Leighton was not compensated from the grant in 2021 or 2022. In 2023, Leighton was compensated \$4,521.63 in salary and \$1,262.15 in fringe for 2 months of labor. It is projected that Leighton will be compensated an annual salary of \$40,000.00 and \$6,400.00 in fringe in 2024, and an annual salary of \$25,000.00 and \$4,000.00 in fringe in the remaining grant years.

53, 74 Open Position, MAPS Clinical Program Manager

75% effort for salaried employee with an annual salary of \$77,000.00 and \$12,320.00 in fringe for the duration of the study (2025-2027). Responsible for regulatory submission preparation, quarterly grant reports, designing the CMC supply & distribution process, general start-up activities, and ongoing management and oversight of the CRO and other contracted services.

Former program personnel of MAPS and Lykos Therapeutics are listed below.

Line

- 54, 75 Krystal Cohn, Lykos Therapeutics Clinical Program Manager
Responsible for Cannabis Program and CRO Management, manages study timelines, conduct, and deliverables in line with budgets. Ensures Good Clinical Practice (GCP) requirements are followed by CRO and clinical trial sites. Cohn was compensated \$58,916.79 in salary in 2022 and no fringe.
- 55, 76 Julie Blaisdell, Lykos Therapeutics Regulatory Operations Specialist
Responsible for regulatory submissions, annual reports, and Investigator Brochure updates for cannabis to ensure regulatory compliance. Blaisdell was compensated \$3,256.68 in salary and no fringe in 2021 and \$5,112.45 in salary and no fringe in 2022.
- 56, 77 Scott Hamilton, Lykos Therapeutics Director of Biostatistics
Responsible for Statistical Analysis Plan, and ensuring data collection meets the needs of the trial design. Hamilton was compensated \$13,616.57 in salary and no fringe in 2021 and \$32,731.52 in salary and no fringe in 2022.
- 57, 78 Julie Wang, Lykos Therapeutics Senior Clinical Data Scientist
Responsible for setting up biometrics integration with mobile device, exploratory digital data collection with the Oura Ring and machine learning analysis of sleep and heart rate variability data. Wang was compensated \$490.26 in salary and no fringe in 2021 and \$190.62 in salary and no fringe in 2022. .
- 58, 79 Hailee Korotkin, Lykos Therapeutics Senior Manager CMC
Responsible for GMP cannabis supply and distribution. Responsible for international import/export of Schedule 1 controlled substance (cannabis) according to DEA and FDA regulations and quotas, delivery to central U.S. distribution site at Scottsdale Research Institute, and subsequent distribution to clinical trial sites for dispensation to veterans per randomization procedures. Korotkin was compensated \$45,300.87 in salary and no fringe in 2022.
- 59, 80 Brienna Deyo, Lykos Therapeutics Clinical Data Manager

Responsible for planning and configuration of the Electronic Data Capture system for the trial. Deyo was compensated \$151.29 in salary and no fringe in 2021 and \$113.41 in salary and no fringe in 2022.

60, 81 Fairouz Faggouseh, Lykos Therapeutics Regulatory Affairs

Responsible for supporting regulatory submissions and annual reports. Faggouseh was compensated \$742.21 in salary and no fringe in 2021 and \$989.05 in salary and no fringe in 2022.

61, 82 Christina Faulk, Lykos Therapeutics Data Management

Responsible for planning and configuration of the Electronic Data Capture system for the trial. Faulk was compensated \$25.04 in salary and no fringe in 2022.

62, 83 Michelle Pleshe, Lykos Therapeutics Director of Data Management & Services

Responsible for oversight and management of the data management and data science personnel working on the trial. Ensures that information systems required to support the study for VMR purposes are appropriately designed Pleshe was compensated \$12,784.03 in salary and no fringe in 2021 and \$18,634.29 in salary and no fringe in 2022.

63, 84 Monica Taing, Lykos Therapeutics Medical Monitor

Responsible for safety oversight of the clinical trial. Ensures study is done in compliance with regulations, regulatory reporting requirements for adverse events are met, and patient safety is appropriately safeguarded. As a Lykos Therapeutics employee, Taing was compensated \$18,891.05 in salary and no fringe in 2022.

64, 85 Nicholas Miner, Lykos Therapeutics Regulatory Affairs

Responsible for supporting regulatory submissions and annual reports. Miner was compensated \$898.69 in salary and no fringe in 2021 and \$7,022.28 in salary and no fringe in 2022.

65, 86 Jill Harrington Rowe, Lykos Therapeutics Clinical Operations

Responsible for supporting Cannabis Program and CRO management. Rowe was compensated \$17,803.32 in salary and no fringe in 2021 and \$3698.44 in salary and no fringe in 2022.

66, 87 Laura Dawson, Lykos Therapeutics CMC

Responsible for supporting the selection of vendors related to cannabis supply and distribution and managing vendor relationships. Dawson was compensated \$7,258.81 in salary and no fringe in 2021.

67, 88 Leah Bedrosian, Lykos Therapeutics Regulatory Affairs

Responsible for supporting regulatory submissions and annual reports. Bedrosian was compensated \$1,018.95 in salary and no fringe in 2022.

68, 89 Erica Bush, Lykos Therapeutics Clinical Operations

Responsible for supporting Cannabis Program and CRO management. Bush was compensated \$3,748.62 in salary and no fringe in 2022.

69, 90

Shannon Dinapoli, Lykos Therapeutics Regulatory Affairs

Responsible for providing oversight of regulatory submissions and annual reports.
Dinapoli was compensated \$476.40 in salary and no fringe in 2022.

[VMR Supplies, Materials, and Equipment Line](#)

- 102 Clinical Trial Record Retention and Archival
Long term clinical trial record retention costs for 3 clinical trial sites at \$175,000 per month per site for 300 months for a total of \$157,500,00 to be invoiced in 2027. Canadian regulations require that clinical trial records are retained for 25 years (300 months) after the clinical trial is completed.
- d103 Cannabis Drug cost
Purchase cost of \$50,000.00 for 10,800g of Placebo Cannabis at \$4.63 per gram. 360 veterans will be given 2 grams of botanical cannabis per day for 37 days in this clinical trial. The purchase amount includes 20% overage to account for waste during processing. The supplier of the Active Cannabis is waiving the cost of 21,500g of High THC Cannabis for U.S. veterans. An additional \$50,000.00 has been budgeted to this line item to account for longitudinal product stability analyses required by the FDA for a total expense of \$100,000.00.
- 104 Outcome Measure Licensing Fees
The licensing fees for copyrighted clinical outcome measures are included for 1440 screened candidates at \$35.24 per candidate for a total of \$50,740.
- 105 Oura Ring Biometric Surveillance Device
\$85,824.00 purchase cost for 400 units at \$214.56 per Oura Ring Biometric Surveillance Device is included to measure Heart Rate Variability and Sleep stages during the 5-week dosing period, which are important biomarkers for PTSD treatment outcomes. The additional replacement units are necessary in case the original units are lost.

[VMR Contractual Services](#)

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

Line

- 108 Contract Research Organization
The Contract Research Organization RFP was sent to six candidate firms who all indicated initial interest in applying. However, three firms subsequently declined

very close in time to the due date, resulting in only 2 proposals being obtained in time, and one proposal obtained prior to decision finalization but after the creation of the original budget. The proposals were reviewed by Lykos Therapeutics (previously MAPS PBC). Alira Health was selected in September 2021 because they offered a significantly lower cost and provided the best proposal in terms of timeline, quality, and experience. The projected cost of Alira Health was within \$1,972,964.00, which was originally budgeted for this line item. The proposal that was not submitted to Lykos prior to the deadline was not formally reviewed according to Lykos SOP, however the firm quoted a \$7.5M budget, and therefore was not a competitive offer.

In Q1 2023, MAPS ceased the delegation sponsor responsibilities to Lykos Therapeutics. Because MAPS does not have the scope of internal positions needed to take over the functions previously delegated to Lykos, the scope of the CRO role was expanded. Given the vast discrepancies between the CRO bids received for the initial CRO RFP and selection process, MAPS determined it would be most cost-effective to revise the currently negotiated contract with Alira Health, rather than conduct a new RFP and reassessment of the vendor selection. The expansion of scope includes the reallocation of original budget line items (fully or partially) to the Contractual Services CRO line item. These include: VMR program personnel, Information Systems, Clinical Trial Record Retention and Archival, Central Reader for Digital ECG Data, IRB Fees, Trial Recruitment, Clinical Sites, Mobile Application Development, and Medical Monitor Services. Total budget for CRO services with the expansion of scope and inclusion of all Clinical Trial Site payments through the CRO is \$8,680,670.01.

109 GMP Cannabis Packaging and Processing

Lykos Therapeutics originally sent the GMP Cannabis Packaging and Processing RFP to three candidate firms. The most reasonable quote was obtained by Syqe Med at an estimated cost of \$360,000.00, but did not include expected costs related to international shipping. This estimate was used to inform the original budget proposal. Confirmation of a contractor for cannabis packaging and distribution is pending, though MAPS has explored the possibility of the active cannabis provider, Aqualitas, Inc, performing these services at cost.

110 Precision Psychological Assessments – Independent Rater Pool & Placebo Response Reduction Training

At the time the original application, WCG Analgesic Solutions advertised their services as a sole source contractor for the Placebo Reduction Response Training. After further investigation to the services provided, it was determined that that Precision Psychological Assessments (PPA) includes this training for their independent rater pool as a standard part of inter-rater reliability and can provide appropriate training to clinical sites at low cost. PPA is the most experienced and cost-effective option for both Independent Rater Pool services (~\$953K) and Placebo Reduction Response Training (~\$3K). Contracting directly with PPA, will also reduce the expense of needing a MAPS or CRO staff member to manage the Independent Rater Pool. The lead raters at PPA have over 8 years of experience supervising IR assessments, including CAPS-5 and SDS, on over 5 VA studies, 7 pharmaceutical and industry studies, and all PTSD studies sponsored by MAPS since 2016. The IRs at PPA are primarily doctoral-level clinicians and scientists that continually demonstrate a high-level of scoring reliability, which is critical for ensuring data accuracy for our primary endpoint measure. The Lead Raters specifically helped develop the most updated CAPS measure utilized in the protocol, CAPS-5-R. None of the competing vendors have experience with the CAPS-5-R. To account for the coupling of these services, the budget for Placebo Reduction Response Training has been partially reallocated to the Independent Rater Pool line item. This line item also includes minimal additional budget to account for assessment changes, retraining, and other unanticipated expenses. The total budget for this line item is \$979,500.00.

111 CMC Consultation Services

Lykos Therapeutics contacted 11 vendors for the provision of active cannabis supply. Of the eleven vendors, 5 were not interested, 3 were rejected due to lack of responsiveness, compliance, or reliability, and 3 companies (Aqualitas, Inc, Northern Green Canada, and Tilray) underwent further evaluation. Aqualitas, Inc lacked experience with clinical trial regulations, but their product generally met the specifications. Tilray and Northern Green Canada had more experience with clinical trials, however both companies were ultimately unreliable due to lack of responsiveness. Aqualitas agreed to donate the active cannabis supply, for the study under the terms that MAPS pay for product specification analysis and product packaging at cost.

Lykos determined a compromise would be most effective from a cost and time perspective. Lykos chose Aqualitas, Inc as the active cannabis supplier given the donated product and additional services being provided at cost. For targeted CMC and cannabis guidance, MAPS initiated a limited hourly contract with CMC expert consultant, and former Director of R&D at Tilray, Harpreet Kaur, PhD via her consulting business Rudra Solutions, Inc. MAPS was able to negotiate a discounted rate for services at \$250/hour. Given the lack of interest and the blatant lack of expertise in the field, additional CMC consultants were not able to be assessed in an evaluation process separate from the supplier process. The total budget for CMC Consultation Services is \$107,032.00.

112 Medical Monitor Services

The Medical Monitor, Monica Taing, MD, at Lykos Therapeutics transitioned from a salaried position to a contracted position. When this transition occurred, Dr. Taing began invoicing Lykos Therapeutics for hours spent consulting on MJP2. Over the course of 2 years, 2021-2022, Dr. Monica Taing was paid \$37,600.00 as a contractor. An RFP was not distributed to other contractors due to the fact that her compensation as a contractor was comparable to the compensation of a salaried Medical Monitor employee previously included in the budget. It was also determined that completing a competitive bid process and potentially onboarding a new contractor without prior knowledge of the clinical trial would have required an expenditure of monetary resources in excess of any potential savings. As of January 2023, Medical Monitor services are to be provided by the CRO, and no additional external counsel is required. The total budget for Medical Monitor Services is therefore \$37,600.00.

113 Regulatory Affairs Services

Due to the transition away from delegation to Lykos internal staff, this line item includes Regulatory Affairs support in 2023 to support response to the FDA clinical hold and preparation and attendance at a Type B meeting to discuss the hold with FDA. MAPS expended \$83,649.49 for Regulatory Affairs Services in 2023.

Further, in consideration of the prolonged FDA Clinical Hold, funds were reallocated for Regulatory Affairs Services. An informed RFP was sent to 5 legal firms and 5 CROs for regulatory consultation and support for the FDRR. MAPS received estimated service quotes from 3 legal firms and 2 CROs, 2 CROs declined due to lack of expertise, and 2 legal firms and 1 CRO did not respond. Hyman, Phelps, McNamara, PC (HPM) was selected given that they have the most applicable experience and expertise, best budget projection, and are least likely to invoice for unexpected costs. Further, they provided significantly lower hourly rates compared to the other bids received which will help keep costs down. HPM also has significant experience with Formal Disputes and working with the relevant FDA officers to reach successful outcomes. They provided an initial estimate and strategy for the formal dispute process from inception through the potential removal of the clinical hold. This includes the initial quote of \$120k for the first phase of dispute submission and response. They recommend that our best chance of success

includes attending an FDR meeting to present our case and respond to questions from the appellate officer, estimated at \$50k. They also provided estimates for responses to FDA after the meeting and the final submissions to lift the clinical hold if successful totaling at \$51k. The total for the complete process, including two phases of FDA review, was estimated at \$210k. HPM noted that these were conservative estimates, and the team would strive to have final project costs below these estimates. The total budget for Regulatory Affairs Services is \$300,000.00, including past and projected expenses.

VMR Travel (VMR Staff) Line

- 116 Program Meeting Transportation
Airfare and ground transportation of \$1,100.00 per person for 4 VMR personnel for 3 trips is budgeted for the program for a total of \$13,200.00.
- 117 Program Meeting Meals
The cost of program meals at \$100.00 per person per day for three 3-day trips for four VMR personnel is budgeted for the program for a total of \$4,800.00.
- 118 Program Meeting Lodging
The cost of \$250.00 per person per day for four VMR personnel for three 3-day, 2-night trips is budgeted for the program for a total of \$6,000.00.

Indirect Costs Line

- 123 Indirect Costs
Over the course of 2024-2027, an 5% indirect cost has been budgeted to account for core organizational expenses that are essential for MAPS to be able to house this project. The total budget for indirect costs is \$648,952.50.

Grantee is requesting to amend the existing budget as follows:

Line Item	Budget Category	2021	2022	2023	2024	2025	2026	2027	TOTAL
1	Administrative Expenses								
2	Administrative Personnel (Grant Administration Staff)								
3	<i>Salary</i>								
4	Rick Doblin, Ph.D. MAPS Executive Director	-	-	\$20,198.82	\$25,000.00	\$25,000.00	\$25,000.00	\$25,000.00	\$120,198.82
5	Erin Tasman, MAPS VP of Finance & Philanthropy	-	-	\$6,183.18	\$7,000.00	\$7,000.00	\$7,000.00	\$7,000.00	\$34,183.18

47	Total Administrative Expenses	\$2,681.50	\$334.60	\$98,822.00	\$115,657.40	\$107,822.00	\$102,822.00	\$102,822.00	\$530,961.50
48	VMR Program Expenses								
49	VMR Program Staff								
50	<i>Salary</i>								
51	Allison Coker, MAPS Director of Research	-	-	\$55,256.60	\$70,000.00	\$40,000.00	\$40,000.00	\$40,000.00	\$245,256.60
52	McKenna Leighton, MAPS Clinical Research Manager	-	-	\$4,521.63	\$40,000.00	\$25,000.00	\$25,000.00	\$25,000.00	\$119,521.63
53	Open Position, MAPS Clinical Program Manager	-	-	-	-	\$77,000.00	\$77,000.00	\$77,000.00	\$231,000.00
54	Krystal Cohn, Lykos Therapeutics Clinical Program Manager	-	\$58,916.79	-	-	-	-	-	\$58,916.79
55	Julie Blaisdell, Lykos Therapeutics Regulatory Operations Specialist	\$3,256.68	\$5,112.45	-	-	-	-	-	\$8,369.13
56	Scott Hamilton, Lykos Therapeutics Director of Biostatistics	\$13,616.57	\$32,731.52	-	-	-	-	-	\$46,348.09
57	Julie Wang, Lykos Therapeutics Senior Clinical Data Scientist	\$490.26	\$190.62	\$-	-	-	-	-	\$680.88
58	Hailey Korotkin, Lykos Therapeutics Senior Manager CMC	-	\$45,300.87	-	-	-	-	-	\$45,300.87
59	Brienna Deyo, Lykos Therapeutics Clinical Data Manager	\$151.29	\$113.41	-	-	-	-	-	\$264.70
60	Fairooz Faggouseh, Lykos Therapeutics Data Management	\$742.21	\$989.05	-	-	-	-	-	\$1,731.26
61	Christina Faulk, Lykos Therapeutics Data Management	-	\$25.04	-	-	-	-	-	\$25.04
62	Michelle Pleshe, Lykos Therapeutics Director of Data Management & Services	\$12,784.03	\$18,634.29	-	-	-	-	-	\$31,418.32
63	Monica Taling, Lykos Therapeutics Medical Monitor	-	\$18,891.05	-	-	-	-	-	\$18,891.05
64	Nicholas Miner, Lykos Therapeutics Regulatory Affairs	\$898.69	\$7,022.28	-	-	-	-	-	\$7,920.97

106		Total VMR Supplies, Materials, & Equipment	\$85,824.00	\$ -	\$ -	\$50,000.00	\$100,740.00	\$ -	\$157,500.00	\$394,064.00
107		VMR Contractual Services								
108		Contract Research Organization	\$393,677.80	\$236,839.46	\$6,631.50	\$543,528.25	\$2,500,000.00	\$2,500,000.00	\$2,500,000.00	\$8,680,677.01
109		GMP Cannabis Packaging and Processing	\$ -	\$ -	\$ -	\$ -	\$360,000.00	\$ -	\$ -	\$360,000.00
110		Independent Rater Pool & Placebo Response Reduction Training	\$ -	\$ -	\$ -	\$ -	\$490,000.00	\$489,500.00	\$ -	\$979,500.00
111		CMC Consultation Services	\$ -	\$32,032.00	\$10,250.00	\$16,187.50	\$16,187.50	\$16,187.50	\$16,187.50	\$107,032
112		Medical Monitor Services	\$28,000.00	\$9,600.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$37,600.00
113		Regulatory Affairs Services	\$ -	\$ -	\$83,649.49	\$200,000.00	\$16,350.51	\$ -	\$ -	\$300,000.00
114		Total VMR Contractual Services	\$421,677.80	\$278,471.46	\$100,530.99	\$759,715.75	\$3,382,538.01	\$3,005,687.50	\$2,516,187.50	\$10,464,809.01
115		VMR Travel (VMR Staff)								
116		Investigator Meeting transportation	\$ -	\$ -	\$ -	\$ -	\$6,600.00	\$6,600.00	\$ -	\$13,200.00
117		Investigator Meeting Meals	\$ -	\$ -	\$ -	\$ -	\$2,400.00	\$2,400.00	\$ -	\$4,800.00
118		Investigator Meeting Lodging	\$ -	\$ -	\$ -	\$ -	\$3,000.00	\$3,000.00	\$ -	\$6,000.00
119		Total EAP Travel	\$ -	\$ -	\$ -	\$ -	\$12,000.00	\$12,000.00	\$ -	\$24,000.00
120		VMR Other								
121		Does Not Apply								
122		Total EAP Other	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
123		Total VMR Program Expenses	\$564,503.66	\$475,341.24	\$163,962.34	\$940,915.75	\$3,655,198.01	\$3,165,607.50	\$2,833,607.50	\$11,799,136.00
124		Total Direct Cost	\$567,185.16	\$475,675.84	\$262,784.34	\$1,056,573.15	\$3,763,020.01	\$3,268,429.50	\$2,936,429.50	\$12,330,097.50
125		<i>Indirect Cost (0.05)</i>	\$ -	\$ -	\$ -	\$162,238.13	\$162,238.13	\$162,238.13	\$162,238.13	\$648,952.50
		TOTAL PROJECT COST	\$567,185.16	\$475,675.84	\$262,784.34	\$1,218,811.28	\$3,925,258.14	\$3,430,667.63	\$3,098,667.63	\$12,979,050.00



STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

GRETCHEN WHITMER
GOVERNOR

MARLON I. BROWN, DPA
DIRECTOR

Attachment B2 – Compressed Budget

Budget Category	Original	Amended
<i>Administrative Expenses</i>		
Administrative Personnel	\$1,006,846	\$ 357,894
Administrative Supplies, Materials, and Equipment	\$173,068	\$ 173,068
Administrative Contractual Services	\$0	\$ 0
Administrative Travel	\$0	\$ 0
Indirect Administrative Expenses	\$0	\$ 648,952
Administrative Expenses TOTAL	\$1,179,914	\$ 1,179,914
<i>VMR Program Expenses</i>		
VMR Program Staff	\$2,127,337	\$ 916,263
VMR Supplies, Materials, and Equipment	\$1,031,231	\$ 394,064
VMR Contractual Services	\$7,811,143	\$10,464,809
VMR Travel	\$80,625	\$ 24,000
VMR Other	\$748,800	\$ 0
Direct Assistance	\$0	\$ 0
VMR Program Expenses TOTAL	\$11,799,137	\$11,799,137
Total Direct Cost	\$11,799,137	\$11,799,137
Indirect Cost	\$1,179,914	\$1,179,914
Total Project Cost	\$12,979,050	\$12,979,050

The maximum amount of grant assistance offered is \$12,979,050. All other terms and conditions of the grant agreement will remain unchanged and in effect.