

**SOM GRANTS
FINANCIAL STATUS REPORT AND/OR PAYMENT REQUEST**

1. Grantee Name		2. Grant Number		3. Reporting Quarter:		4. Fiscal Year:		5. Final Report:		
WSU		370718M & SUB		Q4: 7/1/22-9/30/22		2022		Yes _____ No <u> X </u>		
6. Cost Categories		Salaries	Fringes	Travel	Rent/Util	Supplies	Prng Materia	Equipment Contractua	Other-INC	Total
7. Total Grant Funds Authorized		\$3,080,771	\$844,452			\$2,328,055		\$129,404	\$638,268	\$7,020,950
8. Total Grant Funds										
a. Grant Expenditures Previously Reported		\$403,383	\$113,393			\$17,340		\$599	\$53,471	\$588,186
b. Grant Expenditures this Report Period		\$126,308	\$35,760			\$10,408		\$9,285	\$18,177	\$199,938
c. Program Income										\$0
d. Grant Expenditures to Date (Lines A+B-C)		\$529,691	\$149,153	\$0	\$0	\$27,748	\$0	\$9,884	\$0	\$788,124
e. Unexpended Balance of Grant Funds		\$2,551,080	\$695,299	\$0	\$0	\$2,300,307	\$0	\$119,520	\$0	\$6,232,826
9. Total Match Funds Authorized		\$0	\$0						\$0	\$0
a. Match Expenditures Previously Reported										\$0
b. Match Expenditures this Report Period										\$0
c. Match Expenditures to Date (Lines A+B)				\$0	\$0	\$0	\$0	\$0	\$0	\$0
d. Unexpended Balance of Match Funds		\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
DO NOT FILL OUT THIS SECTION - MIOSHA										
10. Initial Grant Funds Advance Request - 50%										\$3,510,475
11. Grantee Eligible for Next Payment? (Y/N)										N
12. Subsequent Grant Funds Advance Request										\$0
13. Grantee Eligible for Final Payment? (Y/N)										N
14. MIOSHA Grant Fund Holdback <u> 15 </u> % =						\$1,053,143				FINAL PAYMENT \$3,510,475
										TOTAL GRANT PAYMENT \$7,020,950
15. REMARKS:							16. Agency Approval			
							TSD Director's Signature			


 Gerald MacDonal
 Associate Director
 Spa-Finance
 313-577-2852

10/14/22

Wayne State Warriors Marijuana Clinical Research Program: Investigating the Impact of Cannabinoids on Veterans' Behavioral Health

Leslie H. Lundahl, PhD, Lead Principal Investigator

David Ledgerwood, PhD, Co-Principal Investigator

Project Aims:

In this randomized, controlled clinical trial we are recruiting veterans with PTSD who report using cannabis. **We are conducting two studies that are complementary and linked via their aims and methodology.** In **Study 1**, 200 veterans will be randomized into one of four different THC:CBD dose conditions (High THC:High CBD; High THC: Low CBD; Low THC:High CBD, and Low THC:Low CBD) for a 12-week treatment phase. In **Study 2***, 150 veterans will be randomized into *one of three groups*: a control group (n=50) that receives cannabis that is closely matched to their usual product (up to maximum of 25% THC); (2) a THC reduction group (n=50), tailored across three THC concentrations (5%, 10%, or 15% THC) that are approximately 50% lower than the products they currently use; and (3) a THC reduction + 1:1 CBD group (n=50), also including tailored THC concentrations as in Group 2 but with CBD added in a 1:1 THC:CBD ratio. **Both studies** involve assessments weekly and bi-weekly throughout a 12-week treatment phase, and at 3- (post-treatment), 6-, 9, and 12-months post-baseline. **Primary outcomes** include clinical assessments of PTSD symptom severity, mood and anxiety symptoms, and suicidality. **Secondary measures** include (1) neurocognitive function; (2) overall health, sleep quality, pain, healthcare utilization, and quality of life; (3) individual differences in fear learning and extinction associated with PTSD symptom severity; (4) saliva for DNA analysis to examine genetic and epigenetic markers associated with the endocannabinoid system; and, (5) urine, blood, and saliva samples to quantify levels of endocannabinoids and their metabolites (e.g., anandamide [AEA] and 2-AG), as well as THC and CBD and their metabolites, to examine whether these levels vary as a function of THC:CBD dose mixtures and differentially affect outcomes. Data will be analyzed to determine which THC and CBD levels might be associated with the outcome measures. These data will be used to (1) develop a predictive algorithm that will help determine personalized profiles of patients who may be at increased risk for suicide; and, (2) develop a profile of who might most benefit from cannabinoid therapeutics.

(*Please note changes in the Study 2 protocol made after discussion with CRA/LARA, more fully discussed under Delays, below.)

1). Project Milestones

Study recruitment has begun for Study 2. We have conducted initial screenings for 14 participants.

● **Project Progress**

In the third quarter of 2022 we continued to build infrastructure needed to support the logistical operation of study related elements and the majority of our efforts have centered on recruitment, preparing for screening, hiring and training staff members, and obtaining cannabis. In Q3 we attended two Veteran events, Vet Fest 2022 hosted by VetLife and 2022 Stand Down hosted by the 4Vet Organization. We also continued contact with the Detroit Veterans Affairs Administration and are in the process of working with Ann Arbor's Veteran Affairs Administration to discuss recruitment efforts. We've reached out to veteran organizations through Facebook and contacted coordinators

from other veteran organizations. We distributed IRB-approved study flyers and informational brochures to these and similar organizations (Southwest Solutions and Piquette Square) weekly and posted flyers around the Wayne State medical campus. Our recruitment team is working with Wayne State University Veteran organizations, including the Office of Military & Veterans Academic Excellence, where we have also distributed flyers. Advertisements have also been posted on social media and other advertising platforms such as Facebook and Craigslist weekly. Our project website (www.warriorCARE.net) is live and contains information about the studies, how to contact us, news articles, resources, and links to study eligibility surveys. We have screened several potential participants through this source. Our studies are also listed on ClinicalTrials.gov, which provides contact information, as well.

Our full-time recruiter continues to seek out Veteran-related organizations we can approach for referrals and events like job fairs, where we can rent exhibition booths for our research staff to answer questions, provide information, conducting initial screening interviews and schedule in-person screening. We currently have a wait-list of more than 20 Veterans who would like to be contacted for screening.

Following discussion with CRA/LARA officials and stakeholder groups we have revised Study 2 procedures to clarify that this study is consistent with the definition of a clinical trial and to clearly place it under FDA regulatory approval procedures.

We continue to check in with DEA-approved cannabis suppliers to monitor when cannabis product will be available for purchase so we can start these studies (more detail below in "Delay" section).

Finally, our research laboratory has been allocated additional space by the Department of Psychiatry and Behavioral Neurosciences to significantly expand and re-organize. The Substance Abuse Research Division (SARD), which will administer all Wayne State University Veteran Marijuana Research Grants, is in the process of adding more than 3,600 square feet, including 4 new participant testing and interview rooms, a new phlebotomy and biological sample storage room, and a new physiological testing room. This expansion will add office space for 5 new research assistants, 2 new research coordinators, 4 new Postdoctoral Fellows, 10-12 'hot desk' workstations for students and research volunteers, and a new conference room. Once complete, the SARD will occupy an entire floor in the Tolan Park Medical Building located in Detroit, MI and will serve as the largest clinical cannabis research laboratory in Michigan (and possibly the country). In addition, we converted a conference room to create a comfortable waiting room to accommodate caretakers and family members who accompany Veterans on their lab study days. Study days can be long and we want to provide a comfortable and welcoming space, with reading areas, workspaces, and TV/lounge area for Veterans and their family members or caretakers. We also converted an office to a calming room/safe space for participants should they experience any acute anxiety or discomfort during study procedures. This expansion will provide more usable space for our study participants and staff, and demonstrates the commitment of support from the Department to these VMR projects.

• Noteworthy Accomplishments – Identify and describe any milestones reached or noteworthy accomplishments completed during the period.

Recruitment for Study 2 has begun. Although we are revising our procedures for this study, 14 veterans have undergone screening and those who are eligible for the study have agreed to be recontacted for participation once the study has resumed active recruitment and enrollment.

We have been mentioned or appeared in several media stories that led to an early wave of interest by Veterans who want to participate in the studies.

2). Delays – Brief description of problems or delays, real or anticipated, which should be brought to the attention of the Grant Administrator.

Because the procedural changes made to Study 2 require approval by our university IRB, we have stopped enrolling participants into the study while we await IRB approval. However, there has been a great deal of interest in the research projects and we are continuing telephone screening. Currently we have more than 20 Veterans who have agreed to be contacted when we have received IRB approval.

We are in contact with two DEA Schedule I cannabis growers, who still do not have cannabis products available but say they will in the next 2-3 months. We are preparing the FDA IND applications for both and will submit as soon as a grower is ready. We are also starting the import/export process to obtain cannabis from an overseas cannabis grower should we need to pursue that route as other US cannabis researchers are currently doing.

While we await IRB approval for protocol changes and for DEA-approved research cannabis products to become available, we have reduced salary support for research staff members who will resume their duties once the projects are fully underway.

3). Statement concerning any significant deviation from previously agreed-upon Statement of Work.

In Study 2, instead of having Veterans purchase cannabis from a cannabis dispensary, we will be supplying cannabis obtained from a DEA-approved research cannabis supplier.

4). Financial expenditures of grant money and other contributions to the project, in-kind and/or direct funding.

**Wayne State University: Veteran Marijuana Research 2021 Grant
Title: Investigating the Impact of Cannabinoids on Veterans’ Behavioral Health**

CATEGORY	TOTAL BUDGET	Expenses- thru 10/12/22	% of Budget Spent
Personnel/Fringe	3,925,223	676,638	
Equipment	129,404	9,786	
Supplies/Other	2,282,480	25,127	
Computers	45,575	9,321	
Travel	-	-	
DIRECT TOTALS	6,382,682	720,872	11%
Indirect Costs- 10%	638,268	72,308	
BUDGET TOTALS	7,020,950	793,180	11%

Attachments and Other Materials – Provide project materials developed and implemented during the reporting period (e.g. newspaper articles, newspaper advertisements, forms, brochures, announcements, studies, reports, analyses, audits, etc.).”

Detroit News article ([link here](#))

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Leslie H. Lundahl', written in a cursive style.

Leslie H. Lundahl, PhD
Lead/Contact Principal Investigator

October 15, 2022