

**Wayne State Warriors Marijuana Clinical Research Program:  
Cannabinoid Adjunct to Prolonged Exposure & Recovery (CAPER)**

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**Project Aims:**

In this randomized, double-blind, placebo-controlled clinical trial we will recruit veterans with PTSD who report limited prior use of cannabis along with interest in trying cannabis as a therapy. A total of 280 veterans will be randomized into one of four different THC ( $\Delta^9$ -tetrahydrocannabinol:CBD (cannabidiol) dose conditions (THC; CBD; THC+CBD 1:1 ratio; and placebo). All participants will undergo a standardized 10-session prolonged exposure (PE) treatment protocol, consisting of two introductory/preparation sessions followed by eight exposure sessions. One to two sessions will occur each week. Just prior to beginning actual exposure sessions 1-4, participants will receive their assigned THC:CBD (or placebo) dose. We will assess treatment response (e.g., reduced PTSD symptom severity and suicidal ideation) at each subsequent PE visit, to detect rate of improvement, and again at 3-, 6-, and 9-months following treatment to explore long-term effects of PE coupled with THC, CBD, and THC+CBD (in 1:1 ratio) vs. placebo. **Primary outcomes** include treatment response (i.e., clinical assessments of PTSD symptom severity, mood and anxiety symptoms, suicidality, and disability). **Secondary measures** include: (1) neurocognitive and reward decision-making functions (which could moderate the effects of cannabis and PE on treatment outcomes); (2) overall health, sleep quality, pain, healthcare utilization, and quality of life; (3) individual differences in fear reactivity, which has been associated with PTSD symptom severity; (4) saliva for DNA analysis to examine genetic and epigenetic markers associated with the endocannabinoid (eCB) system; and (5) blood, urine, and saliva samples to quantify levels of eCBs 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 in combination with evidence-based behavioral treatment.

**1. Project Milestones – Percent (%) completion of the project objectives**

Study remains in final start-up and pre-enrollment phase. Following IRB approval of Version 2.0 protocol and consent amendments (October 2025), site preparation activities were completed to enable study initiation. Participant enrollment is anticipated to begin after a kick-off meeting.

**2. Project Progress – Brief outline of the work accomplished during the reporting period and the work to be completed during the subsequent reporting period(s).**

**2.1. Current Progress**

Below are specific tasks accomplished during this reporting period.

**2.2. Research personnel**

- Dr. Rabinak and her research staff have completed final study start-up activities in preparation for enrollment.
- Orientation materials and study workflows finalized for onboarding new team members and cross-lab/study team-wide training/kick-off.

- Cannabis preparation and administration procedure training has been completed.
- Clinical staff has completed training on all clinical assessments.

### **2.3. Regulatory**

- IRB Full Board Amendment #6 was approved October 2025 by WSU IRB following FDA-required modifications.
- The IRB approved protocol was submitted to the DEA on October 31, 2025. Additional information was requested by the DEA on December 3, 2025; our response was sent on that same day. No further communications were received from DEA so as of January 4, 2026 the DEA protocol is finalized.
- No outstanding FDA, DEA, NIDA DSP, or IRB regulatory actions required for study initiation.

### **2.4. Protocol**

- Castor EDC platform finalized, validated with sample data, and fully operational for all 21 visits and clinical assessments.
- Standard Operating Procedures (SOPs) for data entry, quality control, safety documentation and visit workflows and orientation modules drafted and distributed for review.
- MRI workflow and personnel readiness completed.
- Following IRB approval in Oct 2025, MRI and data collection infrastructure at Wayne State were finalized and are ready for participant visits.

### **2.5. Supplies/Equipment**

- N/A

### **2.6. Safety**

- Data Safety Monitoring Board (DSMB) charter and safety reporting templates updated to reflect protocol amendments.
- No adverse events or unanticipated safety issues occurred, as enrollment has not yet begun.

### **2.7. Recruitment and Screening**

- Recruitment and screening materials finalized and ready for initiation and enrollment.

### **2.8. Planned Activities during the Next Reporting Period**

- Schedule and conduct a kickoff meeting to harmonize visit cadence, scheduling, safety procedures, and operational processes. A kickoff meeting was requested following IRB approval in October to align operational domains for study initiation, monitor inter-site readiness, and confirm enrollment timelines, and is pending scheduling.
- Finalize scheduling workflows linking PE therapy (including cannabis administration at Tolan Park) with MRI visits.
- Initiate participant recruitment, screening, and baseline visits.

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

N/A – Still in study start-up

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

Startup activities were completed following IRB approval of the amended protocol in early

October. A kickoff meeting has been requested to finalize these activities and align site activation timelines. Upon completion of the kickoff meeting, participant recruitment and screening can begin immediately. Anticipated initiation of enrollment is early Q1 2026.

**4. Statement concerning any significant deviation from the previously agreed-upon Statement of Work.**

None.

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

Please see financial documentation that will be sent directly from Wayne State University Sponsored Programs Administration (SPA).

**6. 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.).”**

N/A

Respectfully submitted,



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