Operation Whole Health — Veterans At Ease Program

Pilot Clinical Outcomes Study: Full Protocol and Forms

Protocol Title: Terrain Restoration in Veterans with Service-Connected Conditions: A Prospective Observational Cohort Study of the Veterans At Ease Nutraceutical Assisted Program

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ClinicalTrials.gov Registration: [To be obtained prior to first enrollment — registration is required before any participant is enrolled]

A NOTE ON THIS DOCUMENT

This protocol is written to pre-registration and IRB-submission standard. Every form embedded here uses validated, peer-reviewed instruments with published scoring keys. Every data point collected has a pre-specified purpose. This is not a marketing document — it is the foundation on which publishable evidence is built. The data this pilot generates, if collected rigorously, will be the most powerful asset Operation Whole Health possesses.

PART I. PROTOCOL OVERVIEW

1. Background and Rationale

Veterans of the United States Armed Forces carry a disproportionate burden of chronic, multifactorial disease arising from toxic environmental exposure, traumatic brain injury, polypharmacy, and inadequate transition support. Conventional psychiatric and primary care models address these conditions largely through symptom management rather than terrain restoration, contributing to cycles of escalating medication burden, physiological dysfunction, and — in the worst cases — suicide.

The Veterans At Ease program at Operation Whole Health applies the Nutraceutical Assisted Programs (NAP) framework: a cascade-sequenced clinical approach that addresses toxic burden, nutritional deficiency, endocrine dysregulation, neuroinflammation, and gut-brain dysfunction as upstream drivers of the conditions veterans are most commonly diagnosed with. Each link in this cascade is documented in the peer-reviewed literature. What has not yet been demonstrated is the integrated effect of the complete NAP protocol delivered as a structured 90-day program.

This pilot study generates that demonstration.

2. Study Objectives

Primary Objective: To measure change in PTSD symptom severity (PCL-5) from baseline to day 90 in veterans participating in the Veterans At Ease 90-Day Terrain Restoration Protocol.

Secondary Objectives:

- Measure change in depression severity (PHQ-9), anxiety severity (GAD-7), sleep quality (ISI), and quality of life (VR-12) from baseline to day 90 and at 6- and 12-month follow-up
- Document change in biomarker panels (inflammatory, metabolic, hormonal, toxic burden, nutrient status) from baseline to day 90
- Document change in total medication burden (medication count, total daily dose equivalents) from baseline to day 90 under prescriber supervision
- Assess safety: adverse events, serious adverse events, tolerability, and study withdrawal rates
- Document the proportion of participants achieving clinically meaningful improvement (≥10-point PCL-5 reduction; a validated minimally clinically important difference)

Exploratory Objectives:

- Examine associations between baseline biomarker profiles and treatment response
- Examine the relationship between toxic exposure history and baseline symptom severity
- Generate effect-size estimates to power a future controlled trial

3. Study Design

Single-arm prospective observational cohort study. Participants receive the full Veterans At Ease 90-Day Terrain Restoration Protocol and are assessed at pre-specified timepoints. There is no placebo arm or randomization at this phase; this is appropriate for a Phase 1 proof-of-concept study designed to generate effect-size estimates and safety data.

Limitations acknowledged and pre-specified: The absence of a control arm means improvement cannot be causally attributed to the protocol. Participants are self-selected. These limitations will be stated fully in any publication and are the explicit rationale for progressing to controlled designs in Phase 2.

4. Sample Size

N = 30 participants (enrolled over up to 12 months; first 30 who meet eligibility criteria and provide consent).

Rationale: A sample of 30 provides adequate precision to estimate a primary effect size with sufficient confidence intervals for publication and for powering a future controlled trial. It is the minimum credible cohort for a peer-reviewed observational study. Expansion to N = 100 occurs in Phase 2.

5. Study Timeline

Phase	Timepoint	Activities
Screening	Day -14 to Day 0	Eligibility review, consent, baseline assessments, lab draw
Active Protocol	Days 1–90	90-Day Terrain Restoration Protocol delivered
Assessment	Day 30	Mid-protocol clinical check-in + instrument battery

Phase	Timepoint	Activities
Assessment	Day 60	Mid-protocol clinical check-in + instrument battery
Completion	Day 90	Final protocol assessment + full instrument battery + repeat lab draw
Follow-up	Month 6	Remote follow-up instrument battery
Follow-up	Month 12	Remote follow-up instrument battery + optional lab draw

6. Setting

Operation Whole Health, Veterans At Ease Program. All clinical assessments conducted by or under the supervision of a licensed clinician. Biomarker testing conducted by a CLIA-certified laboratory.

PART II. ELIGIBILITY

7. Inclusion Criteria

A participant must meet ALL of the following:

1. Veteran of the United States Armed Forces (any branch, any era) OR active-duty service member with commanding officer approval
2. Age 18–70 years at time of enrollment
3. At least one service-connected disability rating from the Department of Veterans Affairs, OR a documented service-connected condition under evaluation
4. Currently taking at least one prescription medication for a service-connected or service-related condition
5. Able and willing to provide written informed consent
6. Able to attend in-person visits at Operation Whole Health for the 90-day active protocol
7. Has a primary care provider or prescribing clinician who has been informed of participation and agrees to supervise any medication changes
8. Willing to authorize release of relevant medical records for study purposes

8. Exclusion Criteria

A participant must NOT meet ANY of the following:

1. Active suicidal ideation with plan or intent within the past 30 days (C-SSRS score indicating high risk at screening — safety referral required; participant may re-screen after stabilization)
2. Active psychosis or manic episode at time of screening
3. Severe alcohol or substance use disorder requiring medically supervised detoxification (may re-screen after completion of detox)
4. Pregnancy or planning to become pregnant during the study period
5. Diagnosed malignancy currently under active treatment
6. Severe renal impairment (eGFR <30) or hepatic failure

7. Acute cardiovascular event (MI, stroke) within the past 90 days
8. Current participation in another clinical trial involving an investigational intervention
9. Any condition that, in the clinical judgment of the site physician, makes participation unsafe

9. Withdrawal Criteria

A participant will be withdrawn (or may voluntarily withdraw) under the following conditions:

1. Participant request at any time, for any reason, without penalty
2. Emergence of an acute safety concern requiring conventional care (participant may re-enroll after resolution at investigator discretion)
3. C-SSRS indicating new high-risk suicidal ideation (immediate safety protocol activated; crisis resources engaged before withdrawal is processed)
4. Investigator judgment that continued participation is not in the participant's best interest
5. Inability to attend required visits (>2 consecutive missed protocol visits)

All withdrawals are documented on Form 25 (Withdrawal/Early Termination Record) regardless of reason.

PART III. INTERVENTION — THE 90-DAY TERRAIN RESTORATION PROTOCOL

10. Protocol Overview

The Veterans At Ease 90-Day Terrain Restoration Protocol is a cascade-sequenced, individualized clinical program addressing the biological terrain drivers identified in the participant's baseline assessment and biomarker profile. The protocol is not a fixed supplement regimen — it is a clinically individualized sequence guided by each participant's specific deficiencies, toxic burden, and functional status.

The protocol is delivered across six domains, sequenced to address upstream drivers before downstream symptoms:

Domain 1 — Toxic Burden Reduction: Evidence-informed approaches to reducing identified toxic load (heavy metals, mycotoxins, environmental chemicals), using clinically indicated and licensed-clinician-supervised methods only.

Domain 2 — Gut Microbiome and Intestinal Integrity: Individualized support for intestinal permeability, dysbiosis, and digestive function based on microbiome assessment findings.

Domain 3 — Nutritional Repletion: Correction of identified deficiencies (vitamin D, B12, magnesium, zinc, omega-3 fatty acids, and others) using evidence-based nutritional interventions, guided by biomarker results.

Domain 4 — Endocrine and Metabolic Stabilization: Addressing thyroid dysfunction, HPA axis dysregulation (cortisol patterns), testosterone deficiency, and metabolic markers under prescribing clinician supervision.

Domain 5 — Neurological and Cognitive Restoration: Evidence-informed support for neuroinflammation, mitochondrial function, and cognitive performance, guided by biomarker findings and validated cognitive assessment.

Domain 6 — Psychological and Lifestyle Integration: Sleep hygiene protocol, structured physical activity guidance, peer support, voluntary spiritual or meaning-based practices, and family psychoeducation (optional).

11. Visit Schedule

Visit	Timeframe	Duration	Content
Screening Visit	Day -14 to -1	90 min	Consent, eligibility, screening assessments, lab requisition
Baseline Visit (V1)	Day 1	120 min	Full baseline assessment, protocol initiation, individualized plan delivery
Week 2 Check-in (V2)	Day 14 ± 3	45 min	Tolerability check, adherence review, early adjustment
Month 1 Assessment (V3)	Day 30 ± 5	90 min	Instrument battery, clinical review, protocol adjustment
Week 6 Check-in (V4)	Day 45 ± 5	45 min	Tolerability check, biomarker interim review (if ordered)
Month 2 Assessment (V5)	Day 60 ± 5	90 min	Instrument battery, clinical review, protocol adjustment
Week 10 Check-in (V6)	Day 75 ± 5	45 min	Pre-completion review
Completion Assessment (V7)	Day 90 ± 5	120 min	Full instrument battery, repeat lab draw, exit interview
6-Month Follow-up	Month 6 ± 2 weeks	45 min (remote OK)	Instrument battery, medication status, adverse event check
12-Month Follow-up	Month 12 ± 2 weeks	45 min (remote OK)	Full instrument battery, optional lab draw

12. Individualization Protocol

Within 7 days of the baseline lab draw, the supervising clinician reviews all biomarker results and generates an **Individualized Terrain Restoration Plan** (documented on Form 16B) specifying, for each domain:

- The specific deficiencies or abnormalities identified
- The evidence-informed interventions selected and their rationale
- Dosing, duration, and monitoring plan
- Any interventions deferred pending prescriber coordination
- The prescriber of record for any medication-related changes

No de-prescribing of any medication occurs without written authorization from the participant's prescribing clinician. All de-prescribing is gradual, supervised, and documented on Form 20.

PART IV. OUTCOME MEASURES

13. Primary Outcome

PCL-5 (PTSD Checklist for DSM-5) — change from baseline to Day 90.

- 20-item self-report; 0–80 scale; higher = more severe
- Minimally clinically important difference (MCID): ≥10-point reduction
- Administered at: Baseline, Day 30, Day 60, Day 90, Month 6, Month 12

14. Secondary Outcomes

PHQ-9 (Patient Health Questionnaire-9) — depression severity

- 9-item; 0–27; MCID: ≥5-point reduction
- Administered at: Baseline, Day 30, Day 60, Day 90, Month 6, Month 12

GAD-7 (Generalized Anxiety Disorder-7) — anxiety severity

- 7-item; 0–21; MCID: ≥4-point reduction
- Administered at: Baseline, Day 30, Day 60, Day 90, Month 6, Month 12

ISI (Insomnia Severity Index) — sleep quality

- 7-item; 0–28; MCID: ≥6-point reduction or category shift
- Administered at: Baseline, Day 30, Day 60, Day 90, Month 6, Month 12

VR-12 (Veterans RAND 12-Item Health Survey) — health-related quality of life; veteran-validated

- 12-item; generates Physical Component Score (PCS) and Mental Component Score (MCS)
- Administered at: Baseline, Day 90, Month 6, Month 12

AUDIT-C (Alcohol Use Disorders Identification Test — Consumption) — alcohol use

- 3-item; 0–12; screening and change monitoring
- Administered at: Baseline, Day 90, Month 6, Month 12

DAST-10 (Drug Abuse Screening Test) — substance use

- 10-item; 0–10; screening and change monitoring
- Administered at: Baseline, Day 90, Month 6, Month 12

C-SSRS (Columbia Suicide Severity Rating Scale) — suicide risk

- Since Last Visit version administered at EVERY visit; Full version at Baseline
- Safety protocol activated for any score indicating ideation with plan or intent

Medication Burden Index — total number of active prescription medications; total morphine milligram equivalents (MMEs) for opioids; total benzodiazepine diazepam equivalents (DBEs); documented from medication reconciliation at each visit

Biomarker Panels — see Form 15; assessed at Baseline and Day 90 (primary comparison); optional at Month 12

15. Safety Outcomes

- Adverse events (AEs): all unexpected symptoms or deterioration occurring during the study period, regardless of attribution
- Serious adverse events (SAEs): hospitalization, emergency department visit, suicidal behavior, death, or any event deemed medically serious by the investigator
- Study withdrawal rate and reasons
- All safety data reported to the NAP Safety Registry

PART V. DATA GOVERNANCE

16. Data Collection and Management

All forms are completed in ink (or electronic equivalent). Each form bears the participant ID, date, visit number, and completing clinician/staff initials. No form is completed from memory — forms are completed at or immediately after the relevant visit.

Source documents (completed forms) are the authoritative record. Any correction to a source document uses a single line through the error (original still legible), the correction written adjacent, initialed and dated by the person making the correction. Correction fluid (white-out) is never used.

Data is entered into the study database within 48 hours of the visit. Double-entry verification is used for primary outcome data.

17. Participant Identification

Each participant is assigned a unique alphanumeric Participant ID at enrollment (format: OWH-VAE-001 through OWH-VAE-030). The participant's name appears only on the Master Enrollment Log, which is stored separately and securely from all other study documents. All forms, databases, and publications use Participant ID only.

18. Data Security

All paper forms stored in a locked file cabinet in a locked room at the Operation Whole Health study site. Electronic data stored on password-protected, encrypted systems. De-identified research data shared with the NAP Outcome Registry in accordance with participant consent and applicable law.

19. Pre-Specified Analysis Plan

The following analysis plan is registered before any participant is enrolled and is not modified after data collection begins:

Primary analysis: Paired t-test comparing PCL-5 total score at Day 90 versus Baseline, with 95% confidence intervals. Two-sided alpha = 0.05.

Secondary analyses: Paired t-tests for PHQ-9, GAD-7, ISI, VR-12 PCS and MCS scores at Day 90 versus Baseline. Bonferroni correction applied for multiple comparisons.

Responder analysis: Proportion of participants achieving MCID on PCL-5 (≥10-point reduction), with 95% confidence interval.

Medication burden: Wilcoxon signed-rank test comparing medication count and MME/DBE equivalents at Day 90 versus Baseline.

Safety analysis: Descriptive statistics for AEs, SAEs, and withdrawal rates.

Missing data: Last observation carried forward (LOCF) for participants who withdraw after at least one post-baseline assessment. Sensitivity analysis using complete-case only. Results published regardless of direction of effect.

PART VI. SAFETY MONITORING

20. Adverse Event Management

An adverse event is any untoward medical occurrence in a study participant, regardless of whether it is considered related to the study intervention. AEs are graded using NCI CTCAE v5.0 (Grade 1–5) and assessed for relatedness to the study protocol (unrelated / possibly related / probably related / definitely related).

All AEs are recorded on Form 19 within 24 hours of the investigator becoming aware of them.

Serious adverse events (Grade 3–5, hospitalization, or suicidal behavior) are reported to the NAP Safety Registry within 24 hours and to the IRB within 7 days.

21. Suicide Safety Protocol

The C-SSRS is administered at every visit. Any score indicating ideation with plan or intent (C-SSRS Item 4 or 5) triggers the following immediate response:

1. Do not leave participant alone
2. Contact the Veterans Crisis Line (988, press 1; or text 838255)
3. Contact participant's treating mental health provider
4. If immediate danger: call 911 / activate emergency services
5. Document fully on Form 19 (Adverse Event Report)
6. Investigator and primary prescriber notified within 1 hour
7. Participant safety plan reviewed and updated before any study activities continue

22. Data Safety Monitoring

The Principal Investigator reviews cumulative safety data monthly. The following stopping rules apply:

- **Stop enrollment** if ≥3 serious adverse events are assessed as probably or definitely related to the study protocol

- **Stop enrollment** if ≥2 suicide attempts occur during the study period
- **Stop enrollment** if any death is assessed as possibly, probably, or definitely related to the study protocol

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PART VII. ETHICS

23. Informed Consent

Informed consent is a process, not a signature. Every participant:

1. Receives Form 1 (Information Sheet and Consent Form) to review at least 48 hours before signing
2. Has opportunity to ask questions of the investigator or a licensed clinician
3. Is told explicitly that participation is voluntary and that withdrawal at any time carries no consequence to their care at Operation Whole Health
4. Signs and dates Form 1 in the presence of a witness

Consent documents are stored in the participant's study file. A copy is provided to the participant.

24. IRB / Ethics Review

This protocol must be reviewed by an Institutional Review Board (IRB) or equivalent independent ethics committee before the first participant is enrolled. Suggested pathway for an independent practice without institutional affiliation: engage a commercial IRB (e.g., WCG IRB, Advarra, or Salus IRB). IRB approval number is recorded on the Master Enrollment Log.

25. ClinicalTrials.gov Registration

The study must be registered at ClinicalTrials.gov before the first participant is enrolled. The NCT number is recorded on every published document and report arising from this study.

PART VIII. ALL STUDY FORMS

FORM 1 — Study Information Sheet and Informed Consent

Study Title: Terrain Restoration in Veterans with Service-Connected Conditions: A Prospective Observational Cohort Study of the Veterans At Ease Nutraceutical Assisted Program

Participant ID: _____ | **Date:** _____

WHAT IS THIS STUDY?

Operation Whole Health is conducting a research study to measure the effects of the Veterans At Ease 90-Day Terrain Restoration Program. We are testing whether a structured, science-based program addressing the biological roots of common veteran health problems — including toxic burden, nutritional deficiency, hormone

imbalance, and inflammation — leads to measurable improvements in PTSD symptoms, depression, anxiety, sleep, and overall health.

WHY IS THIS RESEARCH IMPORTANT?

Veterans are dying at a rate of more than 17 per day by suicide. Existing programs are not enough. This study will generate real clinical data — measured before, during, and after the program — to show what actually works and to share that evidence with other clinicians, researchers, and policymakers.

WHAT WILL HAPPEN IF I PARTICIPATE?

- You will complete a set of questionnaires and a blood/urine/stool lab panel before the program starts, at 30, 60, and 90 days, and at 6 and 12 months afterward.
- You will participate in the full 90-day Veterans At Ease program, visiting the clinic approximately every 2 weeks.
- Your questionnaire scores and lab results will be collected and analyzed as part of the study.
- Your data will be de-identified (your name will not be used) before being analyzed or published.

WHAT ARE THE RISKS?

- The program involves evidence-based nutritional and lifestyle interventions. Risks are low but include possible supplement reactions, detoxification symptoms (fatigue, temporary symptoms as toxic load is reduced), or emotional responses as trauma-related issues are addressed.
- Any adverse effects will be documented and addressed promptly by your clinical team.
- If you experience a mental health crisis, you will be connected immediately with emergency resources.

WHAT ARE THE BENEFITS?

- You will receive the full Veterans At Ease 90-day program, including individualized clinical assessment and a personalized terrain restoration plan.
- You may experience improvement in PTSD symptoms, mood, sleep, energy, and overall health.
- You will contribute to evidence that could help thousands of other veterans.

IS PARTICIPATION VOLUNTARY?

Yes. Your participation is completely voluntary. You may withdraw at any time without any effect on your care at Operation Whole Health.

WILL MY INFORMATION BE KEPT PRIVATE?

Your personal information will never appear in research reports. You will be identified only by a participant ID number. Your data will be stored securely and de-identified before being shared with any research registry.

WHO DO I CONTACT WITH QUESTIONS?

Michael Andrew Jones, Operation Whole Health | michael@operationwholehealth.org

Veterans Crisis Line: 988, press 1 | Text: 838255

CONSENT

I have read this information sheet. I have had the opportunity to ask questions. I understand that my participation is voluntary and that I may withdraw at any time.

I consent to:

☐ Participate in the 90-Day Veterans At Ease Terrain Restoration Program as a research participant

☐ Complete all study questionnaires at the scheduled timepoints

☐ Have my blood, urine, and stool analyzed as part of the study biomarker panel

☐ Have my de-identified data included in the NAP Outcome Registry for research purposes

☐ Allow the study team to contact my prescribing clinician to coordinate any medication changes

Participant signature: _____ Date: _____

Participant printed name: _____

Witness signature: _____ Date: _____

Witness printed name: _____

Investigator/designee signature: _____ Date: _____

FORM 2 — Eligibility Screening Checklist

Participant ID: _____ | Screened by: _____ | Date: _____

Instructions: Circle YES or NO for each item. A participant must have YES on all Inclusion items and NO on all Exclusion items to be eligible. Any NO on Inclusion or YES on Exclusion = SCREEN FAIL. Document reason on last line.

INCLUSION CRITERIA

#	Criterion	Met?
I-1	Veteran of US Armed Forces (any branch, any era) OR active-duty with CO approval	YES / NO
I-2	Age 18–70 years	YES / NO
I-3	At least one service-connected disability rating OR service-connected condition under evaluation	YES / NO
I-4	Currently taking ≥1 prescription medication for a service-connected or service-related condition	YES / NO
I-5	Able and willing to provide written informed consent	YES / NO
I-6	Able to attend in-person visits at Operation Whole Health for 90 days	YES / NO
I-7	Has a primary prescribing clinician who has been informed of participation and agrees to supervise medication changes	YES / NO

#	Criterion	Met?
I-8	Willing to authorize release of relevant medical records	YES / NO

EXCLUSION CRITERIA

#	Criterion	Present?
E-1	Active suicidal ideation with plan or intent within past 30 days	YES / NO
E-2	Active psychosis or manic episode at screening	YES / NO
E-3	Severe AUD/SUD requiring medically supervised detoxification	YES / NO
E-4	Current pregnancy or planning pregnancy during study period	YES / NO
E-5	Malignancy under active treatment	YES / NO
E-6	Severe renal impairment (eGFR <30) or hepatic failure	YES / NO
E-7	Acute MI or stroke within past 90 days	YES / NO
E-8	Currently enrolled in another interventional clinical trial	YES / NO
E-9	Any condition making participation unsafe per investigator clinical judgment	YES / NO

ELIGIBILITY DETERMINATION:

☐ **ELIGIBLE** — meets all inclusion, meets no exclusion → proceed to consent and enrollment

☐ **SCREEN FAIL** — criterion failed: _____

☐ **NEEDS CLINICAL REVIEW** before determination — reason: _____

Screening clinician signature: _____ **Date:** _____

FORM 3 — Enrollment Confirmation and Baseline Demographics

Participant ID: _____ | **Enrollment Date:** _____ | **Visit:** Screening/Baseline

Enrolled by: _____ | **IRB Approval #:** _____ | **NCT #:** _____

SECTION A — SERVICE HISTORY

Branch of service: ☐ Army ☐ Navy ☐ Marine Corps ☐ Air Force ☐ Coast Guard ☐ Space Force ☐ National Guard ☐ Reserve

Era(s) of service (check all that apply):

☐ Vietnam ☐ Gulf War ☐ OEF/OIF/OND (post-9/11) ☐ Other: _____

Total years of service: ___ | Discharge status: ☐ Honorable ☐ General ☐ Other: ____

Combat deployment: ☐ Yes ☐ No | Number of deployments: ___

SECTION B — DEMOGRAPHICS

Date of birth: _____ | Age at enrollment: ___ | Sex assigned at birth: ☐ M ☐ F ☐ Intersex

Gender identity: ☐ Man ☐ Woman ☐ Non-binary ☐ Prefer not to say ☐ Other: _____

Race (check all that apply): ☐ White ☐ Black/African American ☐ Hispanic/Latino ☐ Asian ☐ American Indian/Alaska Native ☐ Pacific Islander ☐ Other ☐ Prefer not to say

Highest education: ☐ Some high school ☐ High school/GED ☐ Some college ☐ Associate's ☐ Bachelor's ☐ Graduate degree

Current employment: ☐ Employed full-time ☐ Employed part-time ☐ Unemployed ☐ Disabled ☐ Retired ☐ Student

Living situation: ☐ Own/rent home ☐ With family ☐ Transitional housing ☐ Homeless or at risk ☐ Other

SECTION C — SERVICE-CONNECTED CONDITIONS

List all current VA service-connected disability ratings:

Condition	Rating %	Year Established

Combined disability rating: ___%

SECTION D — PRIOR TREATMENT

Prior mental health treatment: ☐ Yes ☐ No | If yes, type(s): _____

Prior hospitalization for mental health: ☐ Yes ☐ No | Number of lifetime hospitalizations: ___

Prior suicide attempts: ☐ Yes ☐ No | Number: ___ | Most recent: _____

Current VA care: ☐ Yes ☐ No | VA facility: _____

Staff signature: _____ **Date:** _____

FORM 4 — Baseline Clinical Interview

Participant ID: _____ | **Date:** _____ | **Clinician:** _____

Instructions: Clinician-administered structured interview. Record participant responses. This form supplements the validated self-report instruments — it is NOT a replacement.

SECTION A — CHIEF CONCERNS

In your own words, what are the 3 most important health problems you want to address in this program?

1. _____
2. _____
3. _____

How long have these problems been present? _____

What treatments have you tried for these problems? _____

_____

What has helped, even partially? _____

What has definitely NOT helped? _____

SECTION B — CURRENT SYMPTOM REVIEW

Rate the following on a scale of 0 (none) to 10 (severe) RIGHT NOW:

Symptom	Score (0–10)	Notes
PTSD/trauma symptoms		
Depression/low mood		
Anxiety/worry		
Sleep problems		
Chronic pain		
Fatigue/low energy		
Brain fog / difficulty thinking		
Irritability / anger		
Alcohol use (concern level)		
Drug/substance use (concern level)		
Suicidal thoughts (currently)		
Physical health (overall)		

SECTION C — HEALTH HISTORY

Diagnosed medical conditions (list all):

_____

_____

Prior surgeries or significant medical events:

_____

Family history (first-degree relatives): ☐ Cardiovascular disease ☐ Diabetes ☐ Cancer ☐ Mental health conditions ☐ Substance use ☐ Neurodegenerative disease

SECTION D — LIFESTYLE FACTORS

Current physical activity: ☐ None ☐ Light (walking) ☐ Moderate (3–5 days/week) ☐ Vigorous (6–7 days/week)

Sleep: Average hours per night: ___ | Sleep quality (1–10): ___ | Shift work or disrupted schedule: ☐ Yes ☐ No

Diet pattern: ☐ Standard American ☐ Mediterranean ☐ Low-carb/keto ☐ Vegetarian/vegan ☐ Other: ____

Alcohol: Drinks per week: ___ | Type: _____ | Binge episodes (5+/4+ drinks): ☐ Yes ☐ No

Tobacco: ☐ Never ☐ Former (quit: ____) ☐ Current | Pack-years: ___

Other substance use: _____ | Frequency: _____

Clinician signature: _____ **Date:** _____

FORM 5 — PCL-5 (PTSD Checklist for DSM-5)

Participant ID: _____ | **Date:** _____ | **Visit:** _____

Source: Weathers, F.W., et al. (2013). National Center for PTSD, VA. Public domain.

Instructions: Below is a list of problems that people sometimes have in response to a very stressful experience. Please read each problem carefully and then circle one of the numbers to the right to indicate how much you have been bothered by that problem in the **past month**.

0 = Not at all | 1 = A little bit | 2 = Moderately | 3 = Quite a bit | 4 = Extremely

#	In the past month, how much were you bothered by:	Score
1	Repeated, disturbing, and unwanted memories of the stressful experience?	0 1 2 3 4
2	Repeated, disturbing dreams of the stressful experience?	0 1 2 3 4
3	Suddenly feeling or acting as if the stressful experience were actually happening again (as if you were actually back there reliving it)?	0 1 2 3 4
4	Feeling very upset when something reminded you of the stressful experience?	0 1 2 3 4
5	Having strong physical reactions when something reminded you of the stressful experience (e.g., heart pounding, trouble breathing, sweating)?	0 1 2 3 4
6	Avoiding internal reminders of the stressful experience (e.g., thoughts, feelings, or physical sensations)?	0 1 2 3 4
7	Avoiding external reminders of the stressful experience (e.g., people, places, conversations, activities, objects, or situations)?	0 1 2 3 4
8	Trouble remembering important parts of the stressful experience?	0 1 2 3 4
9	Having strong negative beliefs about yourself, other people, or the world (e.g., having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)?	0 1 2 3 4
10	Blaming yourself or someone else for the stressful experience or what happened after it?	0 1 2 3 4
11	Having strong negative feelings such as fear, horror, anger, guilt, or shame?	0 1 2 3 4
12	Loss of interest in activities that you used to enjoy?	0 1 2 3 4
13	Feeling distant or cut off from other people?	0 1 2 3 4
14	Trouble experiencing positive feelings (e.g., being unable to feel happiness or have loving feelings for people close to you)?	0 1 2 3 4
15	Irritable behavior, angry outbursts, or acting aggressively?	0 1 2 3 4

#	In the past month, how much were you bothered by:	Score
16	Taking too many risks or doing things that could cause you harm?	0 1 2 3 4
17	Being "super alert" or watchful or on guard?	0 1 2 3 4
18	Feeling jumpy or easily startled?	0 1 2 3 4
19	Having difficulty concentrating?	0 1 2 3 4
20	Trouble falling or staying asleep?	0 1 2 3 4

PCL-5 TOTAL SCORE: _____ (sum of items 1–20; range 0–80)

Score interpretation: 0–10 = minimal; 11–20 = mild; 21–33 = moderate; 34–49 = moderately severe; 50–80 = severe

Probable PTSD diagnosis (provisional, not clinical): ≥31 with DSM-5 symptom criteria met = likely PTSD

Completed by: ☐ Participant self-report ☐ Clinician-administered

Staff initials: ___ **Date verified:** _____

FORM 6 — PHQ-9 (Patient Health Questionnaire-9)

Participant ID: _____ | **Date:** _____ | **Visit:** _____

Source: Kroenke K, Spitzer RL, Williams JBW. (2001). J Gen Intern Med. Public domain.

Instructions: Over the **last 2 weeks**, how often have you been bothered by any of the following problems?

0 = Not at all | 1 = Several days | 2 = More than half the days | 3 = Nearly every day

#	Problem	Score
1	Little interest or pleasure in doing things	0 1 2 3
2	Feeling down, depressed, or hopeless	0 1 2 3
3	Trouble falling or staying asleep, or sleeping too much	0 1 2 3
4	Feeling tired or having little energy	0 1 2 3
5	Poor appetite or overeating	0 1 2 3
6	Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0 1 2 3
7	Trouble concentrating on things, such as reading the newspaper or watching television	0 1 2 3

#	Problem	Score
8	Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0 1 2 3
9	Thoughts that you would be better off dead, or of hurting yourself in some way	0 1 2 3

PHQ-9 TOTAL SCORE: _____ (sum items 1–9; range 0–27)

Score interpretation: 1–4 = minimal; 5–9 = mild; 10–14 = moderate; 15–19 = moderately severe; 20–27 = severe

ACTION REQUIRED: If Item 9 score ≥ 1, administer C-SSRS immediately and document on Form 12.

☐ Item 9 = 0 (no action required) ☐ Item 9 ≥ 1 → C-SSRS administered: ☐ Yes | C-SSRS result: _____

Staff initials: ___ **Date verified:** _____

FORM 7 — GAD-7 (Generalized Anxiety Disorder-7)

Participant ID: _____ | **Date:** _____ | **Visit:** _____

Source: Spitzer RL, et al. (2006). Arch Intern Med. Public domain.

Instructions: Over the **last 2 weeks**, how often have you been bothered by the following problems?

0 = Not at all | 1 = Several days | 2 = More than half the days | 3 = Nearly every day

#	Problem	Score
1	Feeling nervous, anxious, or on edge	0 1 2 3
2	Not being able to stop or control worrying	0 1 2 3
3	Worrying too much about different things	0 1 2 3
4	Trouble relaxing	0 1 2 3
5	Being so restless that it's hard to sit still	0 1 2 3
6	Becoming easily annoyed or irritable	0 1 2 3
7	Feeling afraid, as if something awful might happen	0 1 2 3

GAD-7 TOTAL SCORE: _____ (range 0–21)

Score interpretation: 0–4 = minimal anxiety; 5–9 = mild; 10–14 = moderate; 15–21 = severe

Staff initials: ___ **Date verified:** _____

FORM 8 — ISI (Insomnia Severity Index)

Participant ID: _____ | **Date:** _____ | **Visit:** _____

Source: Morin CM. (1993). Guilford Press. Validated public-use instrument.

Instructions: Please rate the CURRENT (i.e., last 2 weeks) SEVERITY of your insomnia problem(s).

Part A — Severity of sleep onset, sleep maintenance, and early morning awakening problems:

	None	Mild	Moderate	Severe	Very Severe
1. Difficulty falling asleep	0	1	2	3	4
2. Difficulty staying asleep	0	1	2	3	4
3. Problems waking up too early	0	1	2	3	4

Part B:

	Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied
4. How satisfied/dissatisfied are you with your current sleep pattern?	0	1	2	3	4

	Not at All	A Little	Somewhat	Much	Very Much
5. How noticeable to others do you think your sleep problem is?	0	1	2	3	4
6. How worried/distressed are you about your current sleep problem?	0	1	2	3	4
7. To what extent do you consider your sleep problem to interfere with your daily functioning?	0	1	2	3	4

ISI TOTAL SCORE: _____ (sum items 1–7; range 0–28)

Score interpretation: 0–7 = no clinically significant insomnia; 8–14 = subthreshold; 15–21 = moderate clinical insomnia; 22–28 = severe clinical insomnia

Staff initials: ___ **Date verified:** _____

FORM 9 — AUDIT-C (Alcohol Use Disorders Identification Test — Consumption)

Participant ID: _____ | **Date:** _____ | **Visit:** _____

Source: Bush K, et al. (1998). Arch Intern Med. Public domain.

Instructions: Please answer the following questions about your alcohol use.

1. How often do you have a drink containing alcohol?

☐ 0 — Never ☐ 1 — Monthly or less ☐ 2 — 2–4 times a month ☐ 3 — 2–3 times a week ☐ 4 — 4 or more times a week

2. How many standard drinks containing alcohol do you have on a typical day when you are drinking?

☐ 0 — 1 or 2 ☐ 1 — 3 or 4 ☐ 2 — 5 or 6 ☐ 3 — 7 to 9 ☐ 4 — 10 or more

3. How often do you have six or more drinks on one occasion?

☐ 0 — Never ☐ 1 — Less than monthly ☐ 2 — Monthly ☐ 3 — Weekly ☐ 4 — Daily or almost daily

AUDIT-C TOTAL SCORE: _____ (range 0–12)

Positive screen: ≥3 for women; ≥4 for men → flag for further assessment

Staff initials: ___ Date verified: _____

FORM 10 — DAST-10 (Drug Abuse Screening Test)

Participant ID: _____ | Date: _____ | Visit: _____

Source: Skinner HA. (1982). Addictive Behaviors. Validated public-use instrument.

Instructions: These questions refer to drug use in the past 12 months, NOT including alcoholic beverages. Answer YES or NO.

#	Question	Answer	Score
1	Have you used drugs other than those required for medical reasons?	YES / NO	YES=1
2	Do you abuse more than one drug at a time?	YES / NO	YES=1
3	Are you always able to stop using drugs when you want to?	YES / NO	NO=1
4	Have you had "blackouts" or "flashbacks" as a result of drug use?	YES / NO	YES=1
5	Do you ever feel bad or guilty about your drug use?	YES / NO	YES=1
6	Does your spouse (or parent) ever complain about your involvement with drugs?	YES / NO	YES=1
7	Have you neglected your family because of your use of drugs?	YES / NO	YES=1
8	Have you engaged in illegal activities in order to obtain drugs?	YES / NO	YES=1
9	Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?	YES / NO	YES=1
10	Have you had medical problems as a result of your drug use (e.g., memory loss, hepatitis, convulsions, bleeding)?	YES / NO	YES=1

DAST-10 TOTAL SCORE: _____ (range 0–10)

Score interpretation: 0 = no problems; 1–2 = low level; 3–5 = moderate level; 6–8 = substantial level; 9–10 = severe level

Staff initials: ___ Date verified: _____

FORM 11 — VR-12 (Veterans RAND 12-Item Health Survey)

Participant ID: _____ | Date: _____ | Visit: _____

Source: Kazis LE, et al. Veterans RAND 12-item Health Survey. Public domain for non-commercial research use.

Instructions: This survey asks for your views about your health. Please answer every question by marking the answer as indicated.

1. In general, would you say your health is:

☐ 1 — Excellent ☐ 2 — Very good ☐ 3 — Good ☐ 4 — Fair ☐ 5 — Poor

2. The following items are about activities you might do during a typical day. Does your health now LIMIT you in these activities? If so, how much?

Activity	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
b. Climbing several flights of stairs	1	2	3

3. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your PHYSICAL health?

Problem	Yes	No
a. Accomplished less than you would like	1	2
b. Were limited in the kind of work or other activities	1	2

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any EMOTIONAL problems (such as feeling depressed or anxious)?

Problem	Yes	No
a. Accomplished less than you would like	1	2
b. Didn't do work or other activities as carefully as usual	1	2

5. During the past 4 weeks, how much did PAIN interfere with your normal work (including both work outside the home and housework)?

☐ 1 — Not at all ☐ 2 — A little bit ☐ 3 — Moderately ☐ 4 — Quite a bit ☐ 5 — Extremely

6. These questions are about how you feel and how things have been with you during the past 4 weeks. How much of the time during the past 4 weeks:

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Did you feel calm and peaceful?	1	2	3	4	5	6
b. Did you have a lot of energy?	1	2	3	4	5	6
c. Did you feel downhearted and blue?	1	2	3	4	5	6

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

☐ 1 — All of the time ☐ 2 — Most of the time ☐ 3 — Some of the time ☐ 4 — A little of the time ☐ 5 — None of the time

VR-12 Scoring: Requires algorithm (see scoring guide). Generates Physical Component Summary (PCS) and Mental Component Summary (MCS), both normed to mean 50, SD 10. Higher = better health.

PCS Score: _____ MCS Score: _____ Scored by: _____ Date: _____

FORM 12 — C-SSRS (Columbia Suicide Severity Rating Scale)

Participant ID: _____ | Date: _____ | Visit: _____ | Clinician: _____

Source: Posner K, et al. (2011). Am J Psychiatry. © Columbia University. Licensed for clinical/research use at cssrs.columbia.edu.

Use FULL version at Baseline. Use SINCE LAST VISIT version at all subsequent visits.

⚠ SAFETY ALERT: Any affirmative response to Items 4, 5, or 6 requires IMMEDIATE safety protocol activation (see Protocol Section 21). Do not continue the assessment — activate the protocol first.

IDEATION

Ask: "I'd like to ask you a few questions about any thoughts you might have about suicide or hurting yourself."

Item 1 — Wish to be Dead:

"Have you wished you were dead or wished you could go to sleep and not wake up?"

☐ Yes ☐ No | If yes, describe: _____

Item 2 — Non-Specific Active Suicidal Thoughts:

"Have you had any thoughts of killing yourself?"

☐ Yes ☐ No | If yes, describe: _____

Item 3 — Active Suicidal Ideation with Any Methods (No Plan):

"Have you been thinking about how you might do this?"

☐ Yes ☐ No | If yes, describe: _____

⚠ Item 4 — Active Suicidal Ideation with Some Intent to Act:

"Have you had these thoughts and had some intention of acting on them?"

☐ Yes ☐ No | If YES → STOP. Activate safety protocol immediately.

⚠ Item 5 — Active Suicidal Ideation with Specific Plan and Intent:

"Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?"

☐ Yes ☐ No | If YES → STOP. Activate safety protocol immediately.

BEHAVIOR (Past 3 months at Baseline; Since Last Visit at subsequent assessments)

Item 6 — Suicidal Behavior:

Has the participant made a suicide attempt, engaged in self-injurious behavior, or made any preparatory actions?

☐ Yes ☐ No | If YES → STOP. Activate safety protocol immediately.

Type: ☐ Actual attempt ☐ Interrupted attempt ☐ Aborted attempt ☐ Preparatory acts ☐ Non-suicidal self-injury

---

INTENSITY OF IDEATION (complete only if Items 1–3 are endorsed)

Dimension	Rating (1–5)	Notes
Frequency (how often thoughts occur)		
Duration (how long thoughts last)		
Controllability (can they be pushed aside)		
Deterrents (do reasons not to act exist)		
Reasons for ideation		

C-SSRS Summary:

Highest ideation level endorsed: ☐ 0 (none) ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Suicidal behavior present: ☐ Yes ☐ No

Safety protocol activated: ☐ Yes ☐ No | If yes, document on Form 19 and in clinical notes.

Clinician signature: _____ **Date:** _____ **Time:** _____

FORM 13 — Medication and Supplement Inventory

Participant ID: _____ | **Date:** _____ | **Visit:** _____ | **Completed by:** _____

Instructions: List ALL prescription medications, over-the-counter medications, supplements, herbs, and vitamins currently taken. Verify against pharmacy records where possible. Update at every visit.

#	Medication/Supplement Name	Dose	Frequency	Prescriber (if Rx)	Indication	Start Date	Changes since last visit
1							
2							
3							
4							
5							
6							

#	Medication/Supplement Name	Dose	Frequency	Prescriber (if Rx)	Indication	Start Date	Changes since last visit
7							
8							
9							
10							

Opioid medications — total MME/day: _____

Benzodiazepines — total diazepam equivalents/day: _____

Total prescription medication count: _____

Total supplement count: _____

Prescribing clinician(s) notified of enrollment: ☐ Yes ☐ N/A | Name(s): _____

Staff signature: _____ Date: _____

FORM 14 — Toxic Exposure History

Participant ID: _____ | Date: _____ | Completed by: _____ | Visit: Baseline

Instructions: Check ALL that apply. For each checked item, record estimated duration and dates where known.

SECTION A — BURN PIT AND AIRBORNE EXPOSURES

Exposure	Exposed?	Estimated Duration	Location(s) / Base(s)
Open-air burn pits (any size)	☐ Yes ☐ No ☐ Unsure		
Large burn pits (>10 acres)	☐ Yes ☐ No ☐ Unsure		
Smoke from oil well fires	☐ Yes ☐ No ☐ Unsure		
Diesel exhaust / vehicle emissions (heavy)	☐ Yes ☐ No ☐ Unsure		
Jet fuel / aircraft exhaust	☐ Yes ☐ No ☐ Unsure		
Dust storms / sand and particulate matter	☐ Yes ☐ No ☐ Unsure		
Industrial smoke or chemical plant emissions	☐ Yes ☐ No ☐ Unsure		

SECTION B — WATER AND SOIL CONTAMINATION

Exposure	Exposed?	Estimated Duration	Location(s)
Camp Lejeune water (1953–1987)	☐ Yes ☐ No ☐ Unsure		
PFAS / AFFF firefighting foam	☐ Yes ☐ No ☐ Unsure		
Contaminated drinking water (any base)	☐ Yes ☐ No ☐ Unsure		
TCE / PCE solvents	☐ Yes ☐ No ☐ Unsure		

SECTION C — CHEMICAL AND BIOLOGICAL AGENTS

Exposure	Exposed?	Estimated Duration	Context
Agent Orange / herbicides	☐ Yes ☐ No ☐ Unsure		
Sarin / nerve agents (Gulf War)	☐ Yes ☐ No ☐ Unsure		
Pesticides (military-issued or deployment area)	☐ Yes ☐ No ☐ Unsure		
Lead (firing ranges, paint)	☐ Yes ☐ No ☐ Unsure		
Asbestos (shipboard, barracks)	☐ Yes ☐ No ☐ Unsure		
Radiation / nuclear testing sites	☐ Yes ☐ No ☐ Unsure		
Depleted uranium	☐ Yes ☐ No ☐ Unsure		
Mold / mycotoxins (water-damaged buildings)	☐ Yes ☐ No ☐ Unsure		

SECTION D — MEDICATIONS RECEIVED DURING SERVICE

Medication	Received?	Approximate Duration	Notes
Mefloquine (Lariam) — antimalarial	☐ Yes ☐ No ☐ Unsure		
Pyridostigmine bromide (Gulf War)	☐ Yes ☐ No ☐ Unsure		
Anthrax vaccine	☐ Yes ☐ No ☐ Unsure		
Multiple vaccines in single day (5+)	☐ Yes ☐ No ☐ Unsure		
K2 (synthetic cannabinoids — if used)	☐ Yes ☐ No ☐ Unsure		

SECTION E — ADDITIONAL OCCUPATIONAL EXPOSURES

Other significant exposure not listed above:

_____

_____

PACT Act eligibility noted: ☐ Yes ☐ No ☐ Already filing | VA PACT Act screening completed: ☐ Yes ☐ No

Staff signature: _____ **Date:** _____

FORM 15 — Baseline Biomarker Lab Requisition

Participant ID: _____ | **Ordering Clinician:** _____ | **Date Ordered:** _____ | **Lab:** _____

Instructions: All panels ordered at Baseline (Day 0) and repeated at Day 90. Optional repeat at Month 12. Check each panel ordered. Record results in the corresponding Results section below (to be completed upon receipt).

PANEL A — STANDARD METABOLIC AND HEMATOLOGIC

☐ Complete Blood Count (CBC) with differential

☐ Comprehensive Metabolic Panel (CMP) — glucose, BUN, creatinine, eGFR, electrolytes, liver enzymes

☐ Lipid panel — total cholesterol, LDL, HDL, triglycerides

☐ HbA1c (glycated hemoglobin)

☐ Fasting insulin

☐ Uric acid

PANEL B — INFLAMMATORY MARKERS

☐ High-sensitivity C-reactive protein (hs-CRP)

☐ Erythrocyte sedimentation rate (ESR)

☐ Homocysteine

☐ Fibrinogen

PANEL C — THYROID AND ENDOCRINE

☐ TSH (thyroid stimulating hormone)

☐ Free T3 (triiodothyronine)

☐ Free T4 (thyroxine)

☐ Reverse T3

☐ TPO antibodies (thyroid peroxidase)

☐ AM cortisol (draw before 9 AM)

☐ DHEA-S (dehydroepiandrosterone sulfate)

☐ Total testosterone

☐ Free testosterone

☐ SHBG (sex hormone binding globulin)

☐ Estradiol (if clinically indicated)

PANEL D — NUTRIENT STATUS

☐ Vitamin D (25-OH-D3)

☐ Vitamin B12 (cobalamin)

☐ Folate (RBC folate preferred)

☐ Magnesium (RBC magnesium — NOT serum)

☐ Zinc (serum)

☐ Ferritin

☐ Iron and TIBC

☐ Omega-3 index (EPA + DHA as % of fatty acids)

PANEL E — TOXIC BURDEN

☐ Heavy metals — blood: lead, mercury, arsenic, cadmium

☐ Heavy metals — urine: 24-hour or spot (specify): _____

☐ Mycotoxin panel — urine (specify lab/panel): _____

☐ Glyphosate — urine

☐ PFAS panel (if burn pit / AFFF exposure documented on Form 14)

PANEL F — NEUROLOGICAL / MITOCHONDRIAL

☐ CoQ10 (coenzyme Q10)

☐ Glutathione (reduced, intracellular)

☐ 8-OHdG (oxidative DNA damage marker) — urine

☐ BDNF (brain-derived neurotrophic factor)

☐ Apolipoprotein E genotype (APOE) — obtain separate consent; one-time test

PANEL G — GUT HEALTH

☐ Comprehensive stool analysis / GI-MAP (specify lab): _____

☐ Zonulin (intestinal permeability marker) — stool or serum

☐ Secretory IgA — stool

LAB RESULTS SUMMARY (complete upon receipt; attach original lab reports)

Panel	Result	Reference Range	Flag (H/L/N)	Date Received

Clinician review of results completed: ☐ Yes | **Date:** _____ | **Clinician initials:** _____

Individualized plan updated based on results: ☐ Yes → see Form 16B | **Date:** _____

FORM 16 — Baseline Provider Assessment and Individualized Terrain Restoration Plan

Participant ID: _____ | **Date:** _____ | **Clinician:** _____ | **License #:** _____

SECTION A — CLINICAL SUMMARY

Summary of baseline clinical findings (narrative): _____

_____

_____

Primary drivers identified based on biomarker and clinical assessment:

Domain	Driver Identified	Severity (1–5)	Priority (1 = highest)
Toxic Burden			
Gut / Microbiome			

Domain	Driver Identified	Severity (1–5)	Priority (1 = highest)
Nutritional Deficiency			
Endocrine / Metabolic			
Neurological / Cognitive			
Psychological / Lifestyle			

SECTION B — INDIVIDUALIZED TERRAIN RESTORATION PLAN (Form 16B)

For each domain where a driver was identified, document the intervention:

Domain 1 — Toxic Burden Reduction Plan:

Agents/approach selected: _____

Evidence basis: _____

Prescriber coordination required: ☐ Yes ☐ No | Prescriber notified: ☐ Yes, Date: _____

Duration: _____ weeks | Monitoring plan: _____

Domain 2 — Gut Microbiome and Intestinal Integrity Plan:

Interventions selected: _____

Duration: _____ weeks | Follow-up testing at: ☐ Day 90 ☐ Other: _____

Domain 3 — Nutritional Repletion Plan:

Deficiencies to address: _____

Interventions selected (evidence-based classes, not brand names): _____

Target levels and re-testing schedule: _____

Domain 4 — Endocrine and Metabolic Plan:

Findings and interventions: _____

Prescriber coordination: ☐ Yes ☐ No | Details: _____

Domain 5 — Neurological and Cognitive Restoration Plan:

Findings and interventions: _____

Cognitive re-testing schedule: ☐ Day 90 ☐ Month 6 ☐ Month 12

Domain 6 — Psychological and Lifestyle Plan:

Sleep protocol: _____

Physical activity plan: _____

Peer support: ☐ Enrolled ☐ Referred ☐ Declined | Notes: _____

Spiritual/meaning-based: ☐ Enrolled ☐ Referred ☐ Declined | Notes: _____

Family psychoeducation: ☐ Scheduled ☐ Completed ☐ Declined | Notes: _____

Clinician signature: _____ **Date:** _____

Participant received copy of plan: ☐ Yes **Date:** _____

FORM 17 — Protocol Delivery Tracking and Visit Note

Participant ID: _____ | **Visit #:** ____ | **Date:** _____ | **Visit Type:** _____ | **Clinician:** _____

SECTION A — VISIT CONDUCT

Visit conducted: ☐ In-person ☐ Telephone ☐ Video

Duration: _____ minutes | Participant arrived: ☐ On time ☐ Late ☐ Rescheduled

SECTION B — ADHERENCE REVIEW

Domain	Participant-reported adherence	Barriers identified	Action taken
Toxic burden protocol	☐ Full ☐ Partial ☐ None		
Gut/microbiome protocol	☐ Full ☐ Partial ☐ None		
Nutritional protocol	☐ Full ☐ Partial ☐ None		
Endocrine/metabolic protocol	☐ Full ☐ Partial ☐ None		
Neurological protocol	☐ Full ☐ Partial ☐ None		
Sleep and lifestyle protocol	☐ Full ☐ Partial ☐ None		

SECTION C — TOLERABILITY AND ADVERSE EVENTS

Any new symptoms or adverse events since last visit? ☐ No ☐ Yes → complete Form 19

New symptom/event: _____

SECTION D — PROTOCOL ADJUSTMENTS

Protocol changes made at this visit: ☐ None ☐ Yes — describe:

_____

Reason for change: _____

SECTION E — C-SSRS (SINCE LAST VISIT)

C-SSRS Since Last Visit administered: ☐ Yes | Highest ideation level: ___ | Behavior present: ☐ Yes ☐ No

Safety protocol activated: ☐ Yes ☐ No

SECTION F — NEXT VISIT

Next scheduled visit date: _____ | Type: _____ | Participant confirmed: ☐ Yes ☐ No

Clinician signature: _____ **Date:** _____

FORM 18 — Interval Assessment Battery (Day 30 / Day 60)

Participant ID: _____ | **Assessment Day:** ☐ Day 30 ☐ Day 60 | **Date:** _____ | **Staff:** _____

Instructions: Administer Forms 5 (PCL-5), 6 (PHQ-9), 7 (GAD-7), 8 (ISI), and 12 (C-SSRS Since Last Visit). Record total scores below. Attach completed individual forms to this summary.

Instrument	Score This Visit	Baseline Score	Change (±)	MCID Met?
PCL-5 (0–80)				☐ Yes (≥10↓) ☐ No
PHQ-9 (0–27)				☐ Yes (≥5↓) ☐ No
GAD-7 (0–21)				☐ Yes (≥4↓) ☐ No
ISI (0–28)				☐ Yes (≥6↓) ☐ No
C-SSRS Highest Ideation		Baseline:		Safety protocol: ☐ N/A ☐ Activated

Medication count this visit: _____ | **Change from baseline:** _____ | **De-prescribing log updated:** ☐ Yes ☐ N/A

Clinical impression (clinician, 2–3 sentences):

_____

_____

Clinician signature: _____ **Date:** _____

FORM 19 — Adverse Event Report

Participant ID: _____ | **AE Report #:** ____ | **Date of AE:** _____ | **Date of Report:** _____ | **Reporting clinician:** _____

SECTION A — EVENT DESCRIPTION

Description of the event (what happened, in clinical detail):

_____

_____

Date/time of onset: _____ | Date/time of resolution (if resolved): _____

Ongoing at time of report: ☐ Yes ☐ No

SECTION B — SEVERITY AND ATTRIBUTION

Severity grade (NCI CTCAE v5.0):

☐ Grade 1 — Mild; no functional impairment

☐ Grade 2 — Moderate; some functional impairment; no intervention required

☐ Grade 3 — Severe; hospitalization or significant functional impairment

☐ Grade 4 — Life-threatening

☐ Grade 5 — Death

Serious AE criteria (check all that apply):

☐ Hospitalization or prolonged hospitalization

☐ Emergency department visit

☐ Suicidal behavior (attempt, interrupted attempt, or preparatory act)

☐ Disability or permanent damage

☐ Life-threatening event

☐ Death

☐ None of the above — non-serious AE

Attribution to study protocol:

☐ Unrelated — clearly due to another cause

☐ Unlikely — temporal relationship only

☐ Possible — consistent with protocol, but other causes equally plausible

☐ Probable — consistent with protocol; other causes less likely

☐ Definite — unambiguous relationship to protocol

SECTION C — ACTION TAKEN

Action taken:

☐ No change to protocol ☐ Protocol modified ☐ Protocol suspended ☐ Participant withdrawn ☐ Emergency referral ☐ Other: ____

Outcome of event:

☐ Resolved without sequelae ☐ Resolved with sequelae ☐ Ongoing ☐ Fatal

SECTION D — REPORTING

Reported to NAP Safety Registry: ☐ Yes | Date: _____

Reported to IRB (if SAE): ☐ Yes ☐ N/A | Date: _____

Reported to participant's primary clinician: ☐ Yes | Date: _____

Clinician signature: _____ **Date:** _____

FORM 20 — De-Prescribing Log

Participant ID: _____ | **Maintained by:** _____ | **Period:** Baseline through Day 90 and follow-up

Instructions: Document every medication change during the study period. De-prescribing (reduction or discontinuation of a prescription medication) may ONLY occur under supervision of and with written authorization from the participant's prescribing clinician. Record every change regardless of who initiated it.

Date	Medication	Change (↑dose / ↓dose / discontinued / new)	Reason	Prescriber name	Prescriber authorization (initials or date of communication)	Participant consent ☐

Medication burden summary:

Metric	Baseline	Day 90	Change
Total prescription medication count			
Total opioid burden (MME/day)			
Total benzodiazepine burden (DBE/day)			
Total psychiatric medication count			

Staff signature: _____ **Date:** _____

FORM 21 — Day 90 Completion Assessment

Participant ID: _____ | **Date:** _____ | **Clinician:** _____

SECTION A — COMPLETION STATUS

☐ **Complete** — participant completed the full 90-day protocol

☐ **Partial completion** — completed ___ % of protocol; reason for partial: _____

☐ **Early termination** — see Form 25 | Termination date: _____

SECTION B — FINAL INSTRUMENT BATTERY

Administer Forms 5, 6, 7, 8, 9, 10, 11, 12 (full C-SSRS), and update Form 13 (medication inventory). Record scores:

Instrument	Score	Baseline Score	Change	MCID Met?	Direction
PCL-5				☐ Yes ☐ No	☐ Improved ☐ Unchanged ☐ Worsened
PHQ-9				☐ Yes ☐ No	☐ Improved ☐ Unchanged ☐ Worsened
GAD-7				☐ Yes ☐ No	☐ Improved ☐ Unchanged ☐ Worsened
ISI				☐ Yes ☐ No	☐ Improved ☐ Unchanged ☐ Worsened
VR-12 PCS				N/A	☐ Improved ☐ Unchanged ☐ Worsened
VR-12 MCS				N/A	☐ Improved ☐ Unchanged ☐ Worsened

Instrument	Score	Baseline Score	Change	MCID Met?	Direction
C-SSRS Highest				Safety: ☐ No concern ☐ Protocol activated	

SECTION C — REPEAT LAB DRAW

Repeat biomarker panel ordered: ☐ Yes | Date drawn: _____ | Lab: _____

Results received and reviewed: ☐ Yes | Date: _____

Lab results attached to file: ☐ Yes

SECTION D — OVERALL CLINICAL IMPRESSION

Global Assessment of Change (clinician-rated):

☐ Very much improved ☐ Much improved ☐ Minimally improved ☐ No change ☐ Minimally worsened ☐ Much worsened ☐ Very much worsened

Narrative clinical impression:

_____

_____

SECTION E — CONTINUATION PLAN

Post-program care plan documented and provided to participant: ☐ Yes

Referrals made: _____

Follow-up schedule confirmed: ☐ 6-month ☐ 12-month | Dates: _____

Clinician signature: _____ **Date:** _____

FORM 22 — Exit Interview (Participant-Completed)

Participant ID: _____ | **Date:** _____ | **Visit:** Day 90

Instructions: Please answer these questions in your own words. Your answers help us improve the program for other veterans. There are no right or wrong answers.

1. How would you describe your experience in the Veterans At Ease program overall?

_____

_____

2. What changed most for you during the program?

_____

_____

3. What was most helpful? What would you change?

Most helpful: _____

Would change: _____

4. Please rate the following aspects of the program:

Aspect	1 (Poor)	2	3	4	5 (Excellent)
Quality of clinical assessment	☐	☐	☐	☐	☐
Clarity of your personalized plan	☐	☐	☐	☐	☐
Staff responsiveness and support	☐	☐	☐	☐	☐
Quality of lab testing and results communication	☐	☐	☐	☐	☐
Peer support / community aspects	☐	☐	☐	☐	☐
Overall program value	☐	☐	☐	☐	☐

5. Would you recommend this program to another veteran?

☐ Definitely yes ☐ Probably yes ☐ Unsure ☐ Probably not ☐ Definitely not

6. Is there anything you feel we missed — something you needed that wasn't offered?

_____

_____

7. Do you have any concerns about continuing your health journey after the program ends?

_____

Thank you for your service, and for your trust in this program. Your data will help us change the standard of care for veterans everywhere.

FORM 23 — 6-Month Follow-Up Assessment

Participant ID: _____ | **Date:** _____ | **Method:** ☐ In-person ☐ Phone ☐ Video | **Staff:** _____

SECTION A — CURRENT STATUS

Current living situation: _____ | Employment status: _____

Currently receiving VA care: ☐ Yes ☐ No | Currently receiving mental health care: ☐ Yes ☐ No

Any hospitalizations since Day 90: ☐ Yes ☐ No | If yes: _____

Any emergency department visits since Day 90: ☐ Yes ☐ No | If yes: _____

SECTION B — INSTRUMENT BATTERY

Administer PCL-5, PHQ-9, GAD-7, ISI, AUDIT-C, DAST-10, and C-SSRS (Since Last Visit):

Instrument	Score	Day 90 Score	Change	Direction
PCL-5				☐ Improved ☐ Unchanged ☐ Worsened
PHQ-9				☐ Improved ☐ Unchanged ☐ Worsened
GAD-7				☐ Improved ☐ Unchanged ☐ Worsened
ISI				☐ Improved ☐ Unchanged ☐ Worsened
AUDIT-C				
DAST-10				
C-SSRS Highest				Safety: ☐ No concern ☐ Protocol activated

SECTION C — MEDICATION STATUS

Current total prescription count: _____ | Change from Day 90: _____

Current MME/day (if applicable): _____ | Current benzodiazepine DBE/day: _____

SECTION D — DURABILITY ASSESSMENT

Has the participant maintained any program practices since Day 90? ☐ Yes ☐ No

Which ones: _____

What has been hardest to maintain: _____

Staff signature: _____ **Date:** _____

FORM 24 — 12-Month Follow-Up Assessment

Participant ID: _____ | **Date:** _____ | **Method:** ☐ In-person ☐ Phone ☐ Video | **Staff:** _____

SECTION A — CURRENT STATUS (same as Form 23, Section A)

Current living situation: _____ | Employment status: _____

Any hospitalizations since 6-month visit: ☐ Yes ☐ No | If yes: _____

Any suicide attempts since 6-month visit: ☐ Yes ☐ No | If yes: _____

SECTION B — INSTRUMENT BATTERY

Administer PCL-5, PHQ-9, GAD-7, ISI, VR-12, AUDIT-C, DAST-10, C-SSRS (Since Last Visit):

Instrument	Score	Baseline Score	Change from Baseline	Direction
PCL-5				☐ Improved ☐ Unchanged ☐ Worsened
PHQ-9				☐ Improved ☐ Unchanged ☐ Worsened
GAD-7				☐ Improved ☐ Unchanged ☐ Worsened
ISI				☐ Improved ☐ Unchanged ☐ Worsened
VR-12 PCS				☐ Improved ☐ Unchanged ☐ Worsened

Instrument	Score	Baseline Score	Change from Baseline	Direction
VR-12 MCS				☐ Improved ☐ Unchanged ☐ Worsened
C-SSRS Highest				Safety: ☐ No concern ☐ Protocol activated

SECTION C — OPTIONAL 12-MONTH LAB DRAW

Repeat biomarker panel offered: ☐ Accepted ☐ Declined

If accepted: Date drawn: _____ | Results received: ☐ Yes | Date: _____

SECTION D — LONG-TERM NARRATIVE

In your own words, how is your health compared to when you started the program a year ago?

Participant response (record verbatim or summarized with permission):

_____

_____

_____

Staff signature: _____ **Date:** _____

FORM 25 — Withdrawal / Early Termination Record

Participant ID: _____ | **Date of Withdrawal:** _____ | **Recorded by:** _____

Reason for withdrawal (check primary reason):

☐ Participant voluntary withdrawal — no reason given

☐ Participant voluntary withdrawal — reason given: _____

☐ Lost to follow-up (unable to contact after ≥3 attempts)

☐ Safety concern — acute mental health crisis (C-SSRS high risk)

☐ Safety concern — medical emergency

☐ Investigator decision — safety

☐ Investigator decision — protocol deviation

☐ Other: _____

Last visit completed: _____ | **Last assessment completed:** _____

Data available for analysis (last-observation-carried-forward): ☐ Yes ☐ No

Participant referred to: _____

Safety confirmed at time of withdrawal: ☐ Yes — participant safe and connected to care

Investigator signature: _____ **Date:** _____

FORM 26 — Aggregate Data Entry Sheet (Registry Submission)

Participant ID: _____ | Completed by: _____ | Date: _____

This form is completed after the Day 90 assessment and again after each follow-up. It is the de-identified data entry vehicle for the NAP Outcome Registry.

Data Element	Baseline	Day 30	Day 60	Day 90	Month 6	Month 12
PCL-5 total						
PHQ-9 total						
GAD-7 total						
ISI total						
VR-12 PCS			N/A			
VR-12 MCS			N/A			
AUDIT-C			N/A			
DAST-10			N/A			
Medication count						
MME/day (opioids)						
DBE/day (benzos)						
hs-CRP			N/A			
Vitamin D (25-OH)			N/A			
Lead (blood)			N/A			
Testosterone (total)			N/A			
TSH			N/A			
Any SAE						
Withdrawal	N/A					

De-identification confirmed: ☐ Yes — no PII included

Registry submission confirmed: ☐ Yes | Date: _____

Staff initials: ___

PART IX. QUICK REFERENCE MATERIALS

Master Visit Checklist

Visit	Forms to Complete
Screening	2 (eligibility), 3 (demographics), 4 (clinical interview), 13 (medications), 14 (exposure history)
Baseline (Day 1)	1 (consent — must precede), 5 (PCL-5), 6 (PHQ-9), 7 (GAD-7), 8 (ISI), 9 (AUDIT-C), 10 (DAST-10), 11 (VR-12), 12 (C-SSRS full), 15 (lab order), 16 (provider assessment + individualized plan)
Week 2 (Day 14)	17 (visit note), 12 (C-SSRS since last)

Visit	Forms to Complete
Month 1 (Day 30)	17 (visit note), 18 (interval battery) = Forms 5, 6, 7, 8, 12
Week 6 (Day 45)	17 (visit note), 12 (C-SSRS since last)
Month 2 (Day 60)	17 (visit note), 18 (interval battery) = Forms 5, 6, 7, 8, 12
Week 10 (Day 75)	17 (visit note), 12 (C-SSRS since last)
Day 90	17 (visit note), 21 (completion assessment), 22 (exit interview), 5, 6, 7, 8, 9, 10, 11, 12 (full), 13 (med update), 15 (repeat labs), 20 (de-prescribing log final), 26 (registry entry)
Month 6	23 (6-month follow-up), 26 (registry update)
Month 12	24 (12-month follow-up), 26 (registry update)
Any adverse event	19 (AE report — within 24 hours)
Any withdrawal	25 (withdrawal record)

Safety Quick Reference

Veterans Crisis Line: 988 → Press 1 | Text: 838255

C-SSRS Action Triggers:

- Item 4 or 5 endorsed (ideation with intent): **STOP. Do not leave alone. Call 988. Call treating clinician. If in danger: 911.**
- Item 6 endorsed (suicidal behavior since last visit): **Same protocol.**
- PHQ-9 Item 9 ≥ 1: **Administer C-SSRS immediately.**

SAE Reporting Timeline:

- NAP Safety Registry: within 24 hours
- IRB: within 7 calendar days
- Participant's treating clinician: within 24 hours

Protocol Version 1.0 | Operation Whole Health | Veterans At Ease Program

Contact: michael@operationwholehealth.org

ClinicalTrials.gov Registration: [Obtain before first enrollment]

IRB Approval: [Obtain before first enrollment]

STRATEGIC FRAMEWORK NOTE (Non-Protocol)

This protocol is designed for immediate IRB submission to a commercial IRB (recommended: WCG, Advarra, or Salus). The ClinicalTrials.gov registration takes approximately 2–4 weeks to process and must be completed

before the first participant is enrolled. Both steps are prerequisites for publishability. The first peer-reviewed publication from this pilot — even a single-site observational cohort result — is the most important document Operation Whole Health can produce. It is what changes everything downstream: the bill, the NAP framework, the fundraising, and the conversations with other clinicians.