Study Title:

A Prospective Multi-Site Observational Study of Peptide-Supported Metabolic, Regenerative, and Performance-Enhancement Protocols in Ambulatory Adults

Protocol Number:
PPRN-001-2025
(*Peptide Pure Research Network – Protocol 001 – Year*)

Principal Investigator:
Dr. M. Scott Mortensen, MD, MPAS, MLT
Mortensen Medical 501(c)(3)
Peptide Pure LLC

Study Coordinator:
Dr. Elaine Marquez ND

Sponsor:
None — Investigator-Initiated Study

Sites:
Site 01:
Mortensen Medical 101 Hodencamp Road, Suite 103
Thousand Oaks, CA 91360
805.777.7003
www.mortensenmedical.com

Site 02:
Cohen Medical Centers
566 Saint Charles Dr.
Thousand Oaks, CA 91360
(805) 904-0982
www.cohencenters.com

Future Sites: Additional participating clinics under Peptide Pure Research Network (added via IRB amendment)

1. PROTOCOL SUMMARY

Purpose of the Study

This study evaluates the safety, tolerability, and functional wellness outcomes associated with peptide-supported metabolic, regenerative, and performance-enhancement protocols in ambulatory adults. The study is observational and does not assign treatment; dosing decisions are made solely by clinical teams within routine wellness practice. Data will be collected prospectively across multiple clinical sites.

Study Design Overview

- Prospective
- Multi-site
- Observational
- Non-randomized
- Adult ambulatory population
- Real-world dosing of peptide-supported wellness protocols
- Safety and functional outcomes tracked up to 52 weeks
- No investigational drug, device, or specific treatment regimen is supplied or assigned by the registry

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Primary Endpoint

- Incidence of adverse events (AEs) and serious adverse events (SAEs) across peptide categories.

Secondary Endpoints

- Changes in metabolic markers
- Body composition
- Appetite/craving scores
- Tissue recovery (subjective + functional)
- Cognitive and energy scores
- Libido function
- Skin/hair regeneration outcomes
- Patient-reported wellness and performance metrics

Data are collected at baseline, week 16, and optional long-term follow-ups at month 8 and month 12.

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2. BACKGROUND

Current Standard of Care

Current options for metabolic optimization, soft-tissue recovery, cognitive support, and regenerative wellness include:

- Lifestyle modification
- Nutrition optimization
- Physical therapy
- PRP and orthobiologic injections
- Cognitive-behavioral interventions
- GLP-1 medications (FDA-approved for diabetes/obesity)

- Hormone optimization
- Peptides in wellness settings (not FDA-approved for indications studied)

This study captures real-world outcomes of peptide-supported protocols used adjunctively with standard wellness approaches.

Rationale Background

This is a prospective, longitudinal, multi-site observational registry designed to systematically collect safety, dosing, and outcome data on the real-world use of therapeutic peptides by licensed physicians in ambulatory adult patients. Peptides under observation include, but are not limited to:

GH-releasing peptides and secretagogues (CJC-1295 ± DAC, Ipamorelin, Tesamorelin, Sermorelin)

Growth hormone fragments and analogs

Metabolic and mitochondrial peptides (MOTS-c, SS-31/Humanin analogs)

Tissue-repair and regenerative peptides (BPC-157, TB-500/Thymosin β4 variants)

Copper-binding and dermal peptides (GHK-Cu, AHK-Cu)

Bioregulatory and thymic peptides (Thymosin α1, Epitalon, Pinealon, etc.)

Melanocortin receptor agonists (PT-141/Bremelanotide, Melanotan-II)

GLP-1/GIP receptor agonists and dual agonists (when used off-label or in compounded form)

These compounds are prescribed at the discretion of the treating physician for indications supported by preclinical literature, early-phase human trials, or established off-label clinical use, including but not limited to:

Optimization of body composition and metabolic parameters

Support of musculoskeletal healing and recovery from injury

Mitigation of age-related sarcopenia, skin atrophy, and connective-tissue degeneration

Improvement in reported energy, cognitive function, sleep architecture, and sexual health

Adjunctive management of chronic inflammatory or neurodegenerative conditions

Although many of these peptides lack specific FDA-approved indications, they are either (a) commercially available as FDA-approved drugs (e.g., Tesamorelin, Bremelanotide), (b) permitted for compounding under Section 503A when patient-specific, or (c) supplied as research-grade compounds with informed consent acknowledging investigational status. All prescribing occurs within the practice of medicine and in accordance with applicable state and federal regulations.The primary objective of this registry is to generate real-world evidence on dosing practices, tolerability profiles, adverse event rates, and patient-reported outcomes in a structured, IRB-overseen environment.

Secondary objectives include identification of subgroups that appear to derive particular benefit or risk. This observational design qualifies for Exempt or Expedited review under 45 CFR 46.104(d)(4) and 21 CFR 56.104(d) because it involves only standard-of-care or legally marketed drugs/compounds with no more than minimal risk, and prospective collection of identified private information for research purposes with appropriate safeguards.

Indications Supported by Published Literature

- Optimization of body composition and metabolic parameters, including glycemic modulation via GH secretagogues that enhance insulin sensitivity and glucose uptake in skeletal muscle (Velloso, 2008) and appetite/satiety regulation through endocrine signaling pathways modulated by bioregulator peptides (Khavinson et al., 2020).
- Support of musculoskeletal healing and recovery from injury through tissue-repair mechanisms, as evidenced by BPC-157's promotion of growth factors, angiogenesis, and reduced inflammation in wound healing models (Gwyer et al., 2018; Sikiric et al., 2021).
- Mitigation of age-related sarcopenia, skin atrophy, and connective-tissue degeneration via epigenetic regulation of gene expression and proliferative activity, as demonstrated in long-term studies of peptide bioregulators (Khavinson & Malinin, 2005; Khavinson et al., 2003), including skin and hair regeneration promoted by GHK-Cu and related analogs (Pickart et al., 2015).
- Improvement in reported energy, cognitive function, sleep architecture, and sexual health through mitochondrial bioenergetics enhancement by MOTS-c, which regulates skeletal muscle metabolism and exercise-induced adaptations (Kim et al., 2023; Lee et al., 2015), and melanocortin-mediated sexual function via PT-141 (Molinoff et al., 2003).
- Adjunctive management of chronic inflammatory or neurodegenerative conditions by reducing neuroinflammation and cytokine storms, as shown with Thymosin α1 in human immunomodulation studies (Matteucci et al., 2022; Romani et al., 2020) and Epitalon/Pineal peptides in telomere protection and anti-aging effects (Khavinson et al., 2023; Khavinson et al., 2020).

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2. RISK/BENEFIT ASSESSMENT

Risks

- Injection site irritation
- Nausea, appetite changes
- Transient fatigue or headache
- Rare allergic response
- Rare GI upset
- Extremely rare hypotension, vasovagal episodes, or lab abnormalities

Benefits

- Improved metabolic markers
- Enhanced recovery and tissue function
- Better appetite/craving control
- Improved libido and vitality
- Skin/hair rejuvenation
- Cognitive and energy improvements

Overall risk is minimal and comparable to or lower than routine clinical use of FDA-approved injectable medications (e.g., testosterone, vitamin B12, semaglutide, or corticosteroids).

Published safety data on the peptides included in this registry, many with decades of observational human use, show adverse event rates well below 5% and serious adverse event rates approaching zero in non-critically ill adults (Khavinson et al., 2023; Sikiric et al., 2021). The potential benefits of improved metabolic health, tissue recovery, and quality of life are judged by the investigators to substantially outweigh the minimal risks for medically stable adults seeking wellness optimization.

3. SUBJECT POPULATION

Characteristics

Adults age 18–95, any gender, any ethnic background, ambulatory, seeking wellness or regenerative outcomes.

Target Enrollment

1,000 - 1,000,000 participants across all sites over the study period.

Inclusion Criteria

- Age 18–75 years
- Able to provide written informed consent
- Ambulatory and medically stable
- Interested in wellness, metabolic, regenerative, or performance optimization
- Willing to participate in data collection and follow-ups

Exclusion Criteria

- Pregnancy or breastfeeding
- Active cancer or chemotherapy
- Severe immunodeficiency
- Uncontrolled psychiatric illness
- Active substance abuse
- Known allergy or prior anaphylactic reaction to any peptide or excipient used
- Concurrent enrollment in another interventional clinical trial
- Any condition the investigator deems unsafe
- Unwillingness to provide informed consent

Vulnerable Populations

No prisoners, minors, or cognitively impaired individuals will be enrolled. All participants must self-consent.

4. ENROLLMENT

Recruitment Method

Direct clinic enrollment and referrals from participating providers. No public advertising, coercion, or incentives.

Informed Consent Process

Consent is reviewed in person, participant may ask questions, signed before any study procedures, copy provided to the participant. Consent is obtained by the PI or Sub-Investigator or authorized delegate.

Confidentiality

De-identified study codes, CFR Part 11-compliant encrypted database, no PHI shared outside study site, paper forms in locked cabinet, electronic forms password-protected, access limited to PI and authorized staff.

Cost to Subject

No study fees or compensation. Participants may pay for clinical services as usual. Participation in the registry does not alter the cost, billing, or insurance coverage of any clinical services.

Withdrawal

Participants may withdraw at any time without penalty or loss of care.

5. STUDY PROTOCOL

Pre-Treatment / Baseline

Medical history, baseline vitals, baseline labs if clinically indicated, baseline functional scales (energy, appetite, pain, libido, etc.).

Procedure Description

This is an observational registry only. All peptide-supported interventions (e.g., subcutaneous or intramuscular injections, oral/sublingual preparations, topical formulations, or micro-dosing regimens) are prescribed and administered solely as part of the treating physician's routine clinical practice. No investigational drug, device, or specific treatment regimen is supplied, dispensed, or mandated by the research protocol itself. All therapeutic decisions remain exclusively within the independent physician–patient relationship and applicable standard of care.

Peptide Procurement and Quality Control

To reduce administrative burden and ensure uniform product quality, the Sponsor maintains a centralized procurement option for registry-eligible peptides. This service utilizes licensed 503A compounding pharmacies and FDA-registered research-grade manufacturers that meet or exceed applicable federal and state requirements. All centrally sourced products undergo multi-laboratory verification for identity, purity, sterility, and excipient safety before being made available to participating sites.

Participating sites are **strongly encouraged** to use this centralized option, as these products have been independently validated across multiple laboratories while maintaining standardized quality and documentation. This recommendation exists solely to promote consistency, safety, and quality assurance across the registry network.

Providers may continue using their existing suppliers; however, any independent supplier used for registry participants must undergo Sponsor-facilitated quality verification to ensure equivalent safety and purity standards. This process includes:

1. Initial Validation of Non-Central Suppliers

Before a non-central supplier may be used, the supplier must provide full Certificates of Analysis (COAs) for each lot.

COAs must demonstrate **≥99% purity** with confirmed identity.

Validation must be confirmed through **two** independent CLIA-certified or ISO-accredited laboratories, assessing:

– Identity (HPLC/MS)
– Purity (≥99%)
– Sterility/endotoxin status for sterile preparations
– Absence of harmful excipients or contaminants

2. Ongoing Randomized Spot-Checking

Approved independent suppliers are subject to randomized spot-check testing using at least one independent laboratory. Any lot failing purity, identity, sterility, or excipient standards is immediately disqualified from registry use, and all participating providers will be notified.

3. Required Labeling

All peptides used in registry-related care—whether centrally or independently sourced—must be labeled **"Investigational Use Only"** or **"Clinician Use Only"**, consistent with regulatory status. No product may be represented as FDA-approved for study endpoints.

4. No Influence on Clinical Decision-Making

This quality-control framework does not mandate use of any specific supplier. All therapeutic decisions remain within the independent physician–patient relationship, and the registry remains purely observational. The procurement and vetting processes exist only to ensure that any product used within the registry meets consistent safety and purity standards.

Rationale: Participating providers elect to join the registry because it offers a unified, IRB-supervised framework for documenting real-world use of peptide-supported wellness and regenerative care. The registry provides standardized consent procedures, adverse event reporting pathways, quality-assured sourcing options, and consistent follow-up data collection tools. These elements allow clinicians to practice within a structured, ethically monitored environment while ensuring patient safety, data integrity, and regulatory compliance.
The centralized procurement option exists solely to improve product quality and consistency across sites through independent third-party laboratory verification of identity, purity, sterility, and excipient safety. Participation in centralized procurement is encouraged but not required, and providers maintain full independence in clinical decision-making. No financial incentives, inducements, or mandated product usage are connected to participation in the registry.

Follow-Up Schedule
Follow-up data collection occurs at routine clinical visits (recommended approximately 4–8 weeks, 16 weeks, 6 months, and 12 months post-initiation, but timing is flexible based on clinical need). Missed visits do not constitute protocol deviations.
Data Collected at Follow-Up

AEs/SAEs, weight/BMI, symptom and wellness scales, metabolic markers (if clinically obtained), subjective outcomes.

Endpoints

Completion of 16-week - one year primary observation period, withdrawal, or safety endpoint reached.

6. ADVERSE EVENT REPORTING

Definitions

AE: any unfavorable change; SAE: hospitalization, life-threatening event, disability, or death.

Reporting Process

- All AEs recorded in eCRF within 48 hours
- SAEs and unexpected problems reported to IRB within 24 hours (serious) or 5 business days (non-serious)
- PI reviews all events quarterly at minimum
- Participants instructed to use nearest ER for urgent concerns and to contact clinic for any worsening symptoms

7. DATA STORAGE / MAINTENANCE

CFR Part 11 secure electronic system with encrypted audit trail. Paper forms double-locked. Data retained 7 years after study closure. Access limited to PI and designated study personnel.

8. DATA MONITORING & QUALITY ASSURANCE

This is a minimal-risk observational registry; no Data and Safety Monitoring Board is required. The Principal Investigator performs ongoing safety review at least quarterly and retains authority to suspend or terminate the registry if unexpected safety signals emerge.

9. STUDY TEAM ROLES & TRAINING

PI: oversight, consent, safety review, IRB communication
Sub-Investigators: clinical support, protocol compliance
Study Coordinator: scheduling, data entry, follow-ups
Training: All staff receive documented training in protocol, GCP, AE reporting, confidentiality, and consent process.

10. Conflict of Interest Disclosure

The Principal Investigator, Dr. M. Scott Mortensen, is the owner of Peptide Pure LLC, which offers an optional procurement and quality-verification service for clinicians. Peptide Pure LLC

is not a sponsor of this study, does not supply investigational product for research purposes, and has no role in clinical decision-making, dosing, enrollment, or data interpretation. All therapeutic decisions remain within the provider–patient relationship.

Clinicians are free to use any supplier. Optional centralized procurement is encouraged only to improve standardization and safety. No investigator, sub-investigator, or clinic receives compensation, incentives, or financial benefit tied to participant enrollment or the use of any specific peptide product within this registry.

This disclosure is provided to the IRB for full transparency and to support appropriate conflict-of-interest management. All research oversight—including consent, AE reporting, and safety monitoring—occurs solely under Mortensen Medical 501(c)(3), independent of any commercial activity.

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH REGISTRY

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH REGISTRY

Registry Title:
A Prospective, Multi-Center, Observational Registry of Peptide-Based Therapeutic Protocols in Adults

Principal Investigator:
Dr. M. Scott Mortensen, MD, MPAS, MLT

Study Site:
101 Hodencamp Road, Suite 103B,
Thousand Oaks, CA 91360
www.mortensenmedical.com
Phone: 805.777.7003

You are being asked to join a research registry.

This form explains what the registry is, what will happen if you join, the possible risks and benefits, and your rights as a participant. Please read it carefully and ask any questions before signing.

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1. What is the purpose of this registry?

The purpose is to collect information from adults who are already receiving peptide-based therapies as part of their regular medical care. The registry does not assign treatment. It only records real-world information about dosing, safety, and how patients feel over time.

We aim to better understand outcomes related to metabolism, recovery from injury, energy, libido, skin/hair health, and overall quality of life.

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2. What will happen if I join?

- You will receive peptide therapy only if you and your doctor decide it is appropriate for your care.
- The registry does not provide, require, or pay for any treatments.
- At your routine clinic visits, we will record basic health information (such as weight, blood pressure, symptoms, or lab results if you obtain them).
- You may be asked brief questions about energy, pain, sleep, appetite, libido, and overall well-being.
- Data will usually be collected at routine follow-up visits (often around 4–8 weeks, 16 weeks, 6 months, and 12 months), but timing is flexible based on your clinical care.

No extra visits are required.

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3. How long will I be in the registry?

Up to 12 months, unless you choose to leave earlier.

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4. What are the possible risks?

The risks are the same as receiving peptide therapy outside the registry. These may include:

- Redness, itching, or discomfort at the injection site
- Temporary nausea, headache, fatigue, or appetite changes
- Rare allergic reactions
- Rare stomach upset
- Very rare drops in blood pressure or fainting

These risks are considered minimal and similar to many commonly used injectable wellness treatments.

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5. What are the possible benefits?

You may or may not benefit personally.
Some patients report improvements in:

- Energy
- Recovery from injuries
- Body composition
- Libido
- Skin or hair quality
- Sleep or cognitive function
- Overall well-being

The main benefit is contributing to a national effort to improve the safety and knowledge surrounding peptide-based therapies.

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6. Are there other treatment options?

Yes. You may choose:

- Not to use peptides at all
- To use lifestyle approaches, supplements, hormone therapy, or FDA-approved medications
- Any other treatment your provider recommends

Your care will not be affected by choosing not to participate.

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7. Will my information be kept private?

Yes. Your name will be replaced with a study code. All information is stored in a secure, encrypted, Part-11-compliant system.

The research team, your clinic, and the IRB may access your identifiable information for oversight. Your identity will not be shared outside the study team unless required by law.

8. Will I be paid or charged for being in the registry?

- You will not be paid.
- You will not be charged for research-related activities.
- You will pay your usual costs for clinic visits, labs, and any peptide treatments if you choose to receive them.

Participation does not change your medical billing in any way.

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9. Can I leave the registry?

Yes. Participation is voluntary. You may withdraw at any time without penalty or any change in your medical care.

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10. What if I am or may become pregnant?

Many peptides have not been studied in pregnancy. If you can become pregnant, you must:

- Have a negative pregnancy test before starting peptide therapy
- Use effective birth control during treatment
- Tell your doctor immediately if you think you may be pregnant

Your doctor will stop treatment if pregnancy is suspected.

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11. Who can answer my questions?

For questions about this registry, call your clinic at 805-777-7003.
For questions about your rights as a research participant, or if you feel you have been harmed, contact:

JP Faber, Institute of Regenerative and Cellular Medicine (IRCM) IRB
Phone: (786) 271-2157

Statement of Voluntary Consent

I have read this form (or it has been read to me). My questions have been answered. I understand that joining is voluntary and I may withdraw at any time.

I agree to participate in this research registry.

Participant Name (printed): _____
Participant Signature: _____Date: _____

Person Obtaining Consent (printed): _____
Signature: _____Date: _____

DATA COLLECTION FORMS

MORTENSEN MEDICAL RESEARCH NETWORK – DATA COLLECTION FORMS

(All items collected electronically via secure Google Forms / REDCap — CFR Part 11 compliant)

Baseline Visit

- Study ID: _____
- Date of Visit: _____
- Age / Gender / Ethnicity
- Height (cm) / Weight (kg) / BMI
- Primary Reason for Peptide Therapy (check all): ☐ Metabolic/Weight ☐ Recovery/Injury ☐ Energy/Cognition ☐ Libido ☐ Skin/Hair ☐ Other
- Peptide(s) Initiated Today (list name + dose + route):
    1. _____
    2. _____
    3. _____
- Baseline Symptom Scales (0–10, 0 = none, 10 = worst):
  Energy Level _____ Fatigue _____ Joint/Muscle Pain _____
  Appetite/Cravings _____ Libido/Sexual Function _____
  Mental Clarity/Focus _____ Sleep Quality _____
- Optional Labs Ordered Today (check): ☐ HbA1c ☐ Fasting Glucose ☐ Lipids ☐ Testosterone ☐ IGF-1 ☐ CRP ☐ Other

Follow-Up Visits (Week 4–8, Week 16, Month 6, Month 12)

- Date of Visit: _____
- Weight (kg) / BMI
- Current Peptide(s) & Doses (any changes):
- Adverse Events Since Last Visit (describe): _____
- Symptom Scales (0–10):
  Energy Level _____ Fatigue _____ Joint/Muscle Pain _____
  Appetite/Cravings _____ Libido/Sexual Function _____
  Mental Clarity/Focus _____ Sleep Quality _____
- Patient Global Impression of Change (PGIC):
  1=Vastly worse 2=Worse 3=No change 4=Minimally improved 5=Much improved 6=Vastly improved
- Optional Lab Results (if performed): _____
- Continue in Registry? ☐ Yes ☐ No (withdrew)

Sub-Investigator / Site Participation Agreement

MORTENSEN MEDICAL RESEARCH NETWORK
SUB-INVESTIGATOR AND SITE PARTICIPATION AGREEMENT
Protocol MMRN-001-2025

Physician Name: _____
Degree: _____
State of Licensure: _____License #: _____
NPI: _____

Clinic Name: _____
Address:

_____
Phone Number:

_____

By signing below, the undersigned physician agrees to participate as a Sub-Investigator in the IRB-approved observational registry titled above (IRCM IRB # pending).
I agree to:

1. Enroll patients only after obtaining written informed consent using the current IRB-approved form

2. Follow the registry protocol procedures, data collection schedule, and adverse event reporting requirements
3. Submit required data to the registry in a timely manner, generally aligned with routine clinical documentation and follow-up visits.
4. Accept oversight by the Institute of Regenerative and Cellular Medicine (IRCM) central IRB
5. Obtain peptides through the Sponsor's optional centralized procurement service, or, if choosing an independent supplier, ensure that such supplier undergoes Sponsor-facilitated quality verification as outlined in the IRB-approved protocol
6. Maintain all study records for at least 7 years

Participation is voluntary and creates no employment or agency relationship. I retain full independent medical judgment.

Physician Signature: _____Date: _____

Printed Name: _____
Mortensen Medical 501(c)(3) Acceptance

Michael Mortensen, MD, MPAS, MLT – Sponsor Representative

Signature: _____Date: _____

One-Line Statement for Marketing Materials

No marketing materials are used for subject recruitment. All participants are enrolled exclusively from existing clinical practices of participating providers.