M5.1 — Informed Consent Template (Compounded Peptide Therapy)

Informed Consent — Compounded Peptide Therapy for Weight Management

Template version: Draft v1, 2026-05-26 **Status:** ⚠️ DRAFT — NOT YET LEGALLY REVIEWED. Do not use clinically until legal counsel has signed off. **Intended use:** Template for clinicians prescribing compounded semaglutide, tirzepatide, or related peptide preparations for weight management.

Document overview for clinicians

This is a template. State-specific modifications may be required. Common areas of state variability include:

- Telehealth-prescribing rules
- Compounded-drug informed consent specifics (some states require additional disclosure)
- Off-label use disclosure requirements
- Patient-attestation requirements
- Witness or notarization requirements

Before using this template: 1. Have it reviewed by your legal counsel for your state 2. Confirm with your malpractice carrier 3. Customize the clinician/practice name fields 4. Add any state-mandated disclosures

The template covers the **clinically substantive** disclosures based on M5.1's safety framework. State-specific legal disclosures must be added by your counsel.

INFORMED CONSENT FOR COMPOUNDED PEPTIDE THERAPY

Patient Name: _____ **DOB:** _____

Clinician: _____ **Practice:** _____

Date of consent: _____

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1. The medication being prescribed

I understand that I am being prescribed a **compounded** preparation of:

- ☐ Semaglutide
- ☐ Tirzepatide
- ☐ Other peptide: _____

The molecule itself (semaglutide / tirzepatide / etc.) is the same active pharmaceutical ingredient as in the FDA-approved branded product (Wegovy / Ozempic / Mounjaro / Zepbound, as applicable). What differs is the **preparation pathway**:

- ☐ 503A state-licensed compounding pharmacy
- ☐ 503B FDA-registered outsourcing facility

I understand that the **compounded preparation is not FDA-approved as a finished drug product**, even though the molecule itself has FDA approval for marketing under brand names. Compounded preparations are regulated under section 503A or 503B of the Federal Food, Drug, and Cosmetic Act, which is a distinct regulatory pathway from FDA new-drug approval.

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2. Why compounded vs branded

My clinician has explained the reasons compounded preparation is being recommended in my case, which may include:

- ☐ Cost
- ☐ Access / supply
- ☐ Insurance coverage limitations
- ☐ Specific dosing requirements not available in commercial formulations
- ☐ Other: _____

I understand that the branded products are also a viable option and that I am not required to use compounded preparation. I have had the opportunity to ask questions about both pathways.

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3. Expected benefits

Based on clinical trial evidence for the active molecule:

- **Semaglutide 2.4 mg weekly** (STEP-1, Wilding 2021, PMID 33567185): average 15% body weight loss at 68 weeks
- **Semaglutide CV indication** (SELECT, Lincoff 2023, PMID 37952131): 20% reduction in major adverse cardiovascular events in eligible patients
- **Tirzepatide** (SURMOUNT-1, Jastreboff 2022, PMID 35658024): up to 20.9% body weight loss at 15 mg at 72 weeks
- **Tirzepatide vs semaglutide** (SURMOUNT-5, 2025): tirzepatide ~6.5 percentage points more weight loss than semaglutide head-to-head

I understand that these averages do not predict my individual response. **Some patients lose more, some lose less.** Some patients are non-responders.

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4. Risks and side effects

I have been informed of and understand the following:

Common side effects

- **Gastrointestinal:** nausea, vomiting, diarrhea, constipation, abdominal pain. These are usually most pronounced after dose increases and improve over 2–4 weeks at each new dose. Roughly 70% of patients experience at least one GI symptom.
- **Reduced appetite, food noise reduction:** the intended therapeutic effect.
- **Fatigue, particularly in the first weeks of each dose step-up.**
- **Injection-site reactions:** mild redness, itching, or soreness.

Serious but rare risks

Pancreatitis. A meta-analysis of 62 randomized trials (Wen 2025, PMID 40988099) found the pooled relative risk of acute pancreatitis on GLP-1 receptor agonists is approximately **1.44** (95% CI 1.09–1.89) compared to comparator. This is statistically significant but modest in absolute terms. If I develop severe upper-abdominal pain radiating to the back, I will stop the medication immediately and seek urgent medical evaluation.

Gallbladder events. Gallstones and cholecystitis occur at increased frequency with GLP-1 receptor agonists, likely related to rapid weight loss.

Thyroid C-cell tumors (medullary thyroid carcinoma, MTC). The FDA boxed warning is based on rodent studies (Bjerre Knudsen 2010, PMID 20203154). **I confirm that I do not have a personal or family history of medullary thyroid cancer or Multiple Endocrine Neoplasia Type 2 (MEN2).** I understand this is an absolute contraindication. The 2026 systematic review of 48 trials and 94,245 patients (Ko 2026, PMID 41359966) found that GLP-1 RAs and dual agonists probably have little or

no effect on thyroid, pancreatic, breast, or kidney cancer risk with moderate-certainty evidence; trial follow-up was relatively short.

Non-arteritic anterior ischemic optic neuropathy (NAION). A recognized but very rare adverse event (~1 case per 10,000 person-years order of magnitude) labeled by the European Medicines Agency in May 2025 for semaglutide. Risk factors include diabetes, sleep apnea, and small optic disc anatomy. **If I experience sudden vision changes or vision loss in one eye, I will seek same-day ophthalmology evaluation.**

Psychiatric / suicidality. Early concerns from social media coverage have NOT been confirmed in rigorous database analysis. The Bezin 2024 case-time-control analysis reported an odds ratio of approximately 0.62 (protective, not harmful). However, I will report any new or worsening mood changes, anxiety, or thoughts of self-harm to my clinician immediately.

Pregnancy. I confirm that: - [ ] I am not currently pregnant - [ ] I am not planning pregnancy within the next ___ months - [ ] If pregnancy occurs or becomes planned, I will notify my clinician immediately and the medication will be discontinued - [ ] I understand that semaglutide requires approximately a **2-month washout** before conception attempts; liraglutide requires approximately **2 days** - [ ] I am using contraception if of reproductive age and not actively planning pregnancy

Other considerations

Lean mass loss. GLP-1 receptor agonists are associated with approximately 25–40% of total weight loss coming from lean mass (not just fat). I understand the importance of: - Adequate dietary protein (~1.2 g/kg body weight daily) - Resistance training 2–3 times weekly - These mitigate lean mass loss substantially

Weight regain on discontinuation. Body weight is a chronically defended physiologic variable. The STEP-1 extension and SURMOUNT-4 data show that **approximately two-thirds of lost weight typically returns within 12 months of discontinuation.** This is not a treatment failure — it reflects the underlying biology. I understand that weight management with peptide therapy is typically a chronic-disease management approach (similar to hypertension or dyslipidemia), and that stopping the medication likely means returning toward baseline weight.

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5. Specific to compounded preparation

I understand that:

- The **active molecule** is the same as in the FDA-approved product.
- **Quality of compounded preparation varies between pharmacies.** My clinician has vetted the compounding pharmacy being used. The quality vetting is documented separately (see clinic Compounding Pharmacy Quality Audit).
- The pharmacy used is:

    - Name: _____
    - State licensure verified: [ ] Yes
    - Per-batch Certificate of Analysis provided: [ ] Yes
    - USP 797 compliance documented: [ ] Yes
    - Cold-chain shipping: [ ] Yes
- **I am responsible for proper storage** of the medication at 2–8°C after reconstitution (if applicable). Storage failures may compromise the medication.
- **If supply is lyophilized (powder requiring reconstitution),** I have received training on reconstitution and self-injection technique (see Reconstitution One-Pager and Self-Injection Technique handouts).
- The **regulatory landscape for compounded GLP-1 RA preparations may change.** What is permissible today may change with FDA action, particularly as the shortage status of the branded molecule changes.

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6. Off-label use disclosure (if applicable)

I understand that the following aspects of my treatment are **off-label** (not within the FDA-approved indication):

- ☐ Use of the molecule for a condition not in the FDA-approved indication
- ☐ Use at a dose outside the FDA-approved range
- ☐ Use in a population (e.g., age, BMI) outside the FDA-approved labeling
- ☐ Other: _____
- ☐ N/A — treatment is consistent with FDA-approved indication

Off-label prescribing is legal and common in medical practice; it does not mean the treatment is experimental or inappropriate. It means the FDA has not specifically reviewed and approved this exact use.

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7. Monitoring plan

My clinician and I have agreed on the following monitoring:

- **Baseline labs:** [ ] complete [ ] pending
- **Follow-up cadence:**
    - ☐ Visit at week 4 (post first dose)
    - ☐ Visit at week 12 (post dose escalation)
    - ☐ Lab recheck at month 3
    - ☐ Lab recheck at month 6

- ☐ Visit/lab recheck at month 12
- ☐ Other: _____

- **Body composition monitoring** (DEXA, BIA, or other): [ ] Yes [ ] No
- **Communication plan:** I have my clinician's preferred contact method for urgent concerns and for non-urgent questions.

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8. Alternatives

I have been informed of alternatives, which may include:

- ☐ FDA-approved branded product (Wegovy, Ozempic, Mounjaro, Zepbound, Saxenda) at full cost or with insurance navigation
- ☐ Lifestyle-only intervention (dietary modification, structured exercise, behavioral support)
- ☐ Other pharmacotherapy options (oral medications, other peptide classes)
- ☐ Bariatric surgery consultation
- ☐ No treatment

I have had the opportunity to ask questions about each alternative.

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9. Cost

Estimated cost of compounded treatment: $_____/month Estimated total cost over first 12 months: $_____

This is not typically covered by insurance. I am responsible for full payment unless otherwise arranged.

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10. Patient questions

I have had the opportunity to ask questions and have all of them answered to my satisfaction. Additional questions or concerns I wish to document:

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11. Acknowledgments and consent

By signing below, I confirm that:

- ☐ I have read this consent in full
- ☐ My clinician has explained the proposed treatment, expected benefits, risks, alternatives, and monitoring plan
- ☐ I have had the opportunity to ask questions and have received satisfactory answers
- ☐ I understand this is a compounded preparation, distinct from the FDA-approved branded product
- ☐ I voluntarily consent to proceed with the proposed treatment
- ☐ I understand I may withdraw consent and discontinue treatment at any time
- ☐ I will notify my clinician of any new health changes, pregnancy, hospitalization, or other significant events while on treatment

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Patient signature: _____ Date: _____

Patient printed name: _____

Clinician signature: _____ Date: _____

Clinician printed name: _____

Witness signature (if required by state): _____ Date: _____

Internal — for clinician's chart only

Item	Confirmed
Baseline labs reviewed	[ ]
MTC / MEN2 history screened	[ ]
Pregnancy status confirmed	[ ]
Pancreatitis history screened	[ ]
Active malignancy screened	[ ]
Severe gastroparesis screened	[ ]
Pancreatic cancer family history screened	[ ]
Patient education materials provided (What to Expect handout, Self-Injection Technique handout)	[ ]

Item	Confirmed
Reconstitution training provided (if compounded lyophilized)	[ ]
Compounding pharmacy quality audit on file	[ ]
Adverse event reporting pathway communicated	[ ]

Template version: Draft v1, 2026-05-26 **Reviewers needed:** Legal counsel (state-specific compliance, off-label disclosure language, witness requirements, malpractice carrier alignment). Dr. Gross (clinical accuracy of risk-disclosure thresholds + safety framing). **Companion documents:** Doc 1 Baseline Labs · Doc 3 Compounding Audit · Doc 4 Reconstitution · Doc 7 What to Expect · Doc 8 Injection Technique · Doc 10 Safety Deep Dive