INFORMED CONSENT FOR GLP RECEPTOR AGONIST MEDICATIONS

This Informed Consent for GLP Receptor Agonist Medications ("Consent Form") is entered into between [HEALTHCARE PROVIDER NAME] ("Provider") and the undersigned patient ("Patient"). This Consent Form establishes the Patient's understanding and authorization for treatment with GLP receptor agonist medication as part of their treatment plan.

1. Medication Information

Prescribed Medication _____

□ GLP-1 Receptor Agonist
□ Dual GIP/GLP-1 Receptor Agonist
□ Triple GIP/GLP-1/Glucagon Receptor Agonist

Dosage Form: □ Injectable □ Oral □ Other: _____

Primary Purpose of Treatment
□ Type 2 Diabetes Management
□ Weight Management
□ Other: _____

Initial Dose _____ **Target Dose** _____ **Titration Schedule** _____

Frequency and Duration _____

FDA Approval Status for Prescribed Use
□ FDA-approved for prescribed use
□ FDA-approved medication being used for non-FDA approved indication (off-label use)
□ Investigational medication (not FDA-approved)

2. Purpose and Mechanism of Action

GLP receptor agonist medications work through one or more of the following mechanisms:

a) **GLP-1 (Glucagon-Like Peptide-1) Receptor Activation** These medications mimic the action of the naturally occurring GLP-1 hormone, which helps regulate blood sugar by stimulating insulin secretion when blood sugar is high, slowing gastric emptying, suppressing glucagon secretion, and increasing feelings of fullness by acting on appetite centers in the brain.

b) **GIP (Glucose-Dependent Insulinotropic Polypeptide) Receptor Activation**: Some medications also target the GIP receptor, which enhances insulin secretion and complements the effects of GLP-1 receptor activation.

c) **Glucagon Receptor Activation**: Triple agonists additionally activate the glucagon receptor, which may potentially increase energy expenditure and enhance weight loss effects beyond what is achieved with GLP-1 or dual GLP-1/GIP receptor agonists.

The potential benefits of treatment may include:

- Improved blood sugar control in type 2 diabetes
- Weight reduction
- Reduced cardiovascular risk
- Decreased appetite and increased feeling of fullness
- Potential improvement in metabolic parameters

3. Risks and Potential Side Effects

The Patient acknowledges understanding the following potential risks and side effects:

Common Side Effects (may affect more than 10% of patients):

- Nausea, vomiting
- Diarrhea or constipation
- Abdominal pain or discomfort
- Decreased appetite
- Indigestion/heartburn
- Fatigue
- Injection site reactions (for injectable forms)

Less Common Side Effects:

- Hypoglycemia (low blood sugar), especially when used with other diabetes medications
- Headache
- Dizziness
- Mild increase in heart rate
- Belching or flatulence
- Gastroesophageal reflux disease (GERD) symptoms

Rare but Serious Side Effects:

- Pancreatitis (inflammation of the pancreas)
- Gastroparesis (delayed stomach emptying)
- Bowel obstruction
- Gallbladder problems (including gallstones)
- Acute kidney injury
- Diabetic retinopathy complications (for patients with type 2 diabetes)
- Hypersensitivity reactions

Warning for Injectable Medications:

- For injectable dual and triple receptor agonists, there may be additional risks that are still being studied in clinical trials.
- Investigational medications may have unknown risks or side effects not yet identified.

Specific Warnings:

- **Thyroid C-cell Tumors** GLP-1 receptor agonists have caused thyroid C-cell tumors (including medullary thyroid carcinoma) in rodent studies. It is unknown whether they cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans. These medications are

contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

4. Patient Acknowledgments

I, the Patient, acknowledge and agree to:

a) Provide a complete and accurate medical history, including all medications, supplements, allergies, and medical conditions.

b) Disclose if I have:

- ☐ A personal or family history of medullary thyroid carcinoma
- ☐ Multiple Endocrine Neoplasia syndrome type 2
- ☐ History of pancreatitis
- ☐ History of diabetic retinopathy
- ☐ History of gallbladder disease
- ☐ Kidney problems
- ☐ Current pregnancy or plans for pregnancy
- ☐ Breastfeeding status

c) Report any adverse reactions or unusual symptoms promptly to the Provider.

d) Follow the prescribed medication schedule and titration plan.

e) Attend all scheduled follow-up appointments for monitoring.

f) Follow recommended dietary and lifestyle modifications.

g) Inform all healthcare providers about my use of this medication.

5. FDA Compliance and Adverse Event Reporting

a) The Patient will report any adverse reactions or side effects to the Provider within 24 hours.

b) The Provider will maintain records of all adverse events as required by FDA regulations.

c) The Provider will report serious adverse events to the FDA MedWatch program as required by law.

d) For investigational medications, additional reporting protocols will be followed as specified in relevant clinical trial guidelines.

6. Alternatives to Treatment

The Patient confirms having been informed of reasonable alternatives to GLP receptor agonist therapy, including:

a) **For Type 2 Diabetes**

- ☐ Other diabetes medications (metformin, SGLT2 inhibitors, sulfonylureas, DPP-4 inhibitors, etc.)
- ☐ Insulin therapy
- ☐ Intensive lifestyle modifications

b) **For Weight Management**

- ☐ Other anti-obesity medications
- ☐ Intensive behavioral therapy
- ☐ Bariatric surgery options
- ☐ Comprehensive lifestyle interventions

7. Special Considerations for Women of Childbearing Age

a) GLP receptor agonist medications are not recommended during pregnancy or while breastfeeding.

b) The Patient agrees to use effective contraception while taking these medications if of childbearing potential.

c) The Patient agrees to notify the Provider immediately if pregnancy occurs or is suspected while on this medication.

8. Cost Information

a) The estimated cost per month is: $_____

b) The Patient understands that insurance may not cover the prescribed medication, particularly for:

- ☐ Off-label uses
- ☐ Weight loss (depending on insurance)
- ☐ Investigational medications

c) The Patient acknowledges responsibility for payment of services not covered by insurance.

9. Privacy and HIPAA Compliance

a) The Provider will maintain the confidentiality of all Patient information in accordance with the Health Insurance Portability and Accountability Act (HIPAA).

b) The Patient authorizes the Provider to communicate with other healthcare providers regarding treatment when necessary for coordinating care.

c) The Provider's Notice of Privacy Practices, provided separately to the Patient, governs the use and disclosure of health information collected during treatment.

d) For investigational medications, the Patient understands that additional sharing of information may be required with research sponsors, institutional review boards, and regulatory authorities.

10. Consent Duration and Revocation

a) This Consent Form is valid for the medication described above for a period not to exceed one year from the date of signing, after which it must be renewed.

b) The Patient has the right to revoke this consent at any time by providing written notice to the Provider.

c) Revocation will not apply to services already rendered but will prevent further medication administration under this Consent Form.

11. Emergency Protocols

a) The Provider maintains appropriate emergency equipment and medications to respond to adverse reactions.

b) In case of a severe adverse reaction, the Patient should:

- Call 911 or go to the nearest emergency room if experiencing severe symptoms
- Contact the Provider at: _____
- Phone: _____

12. For Investigational/Off-Label Use Only

For medications prescribed off-label or those that are investigational:

a) The Patient understands that this medication is being prescribed for a use that is not FDA-approved.

b) The Patient acknowledges that the FDA has not determined that this medication is safe and effective for the specified use.

c) The Patient understands that there may be unknown risks associated with this treatment.

d) For investigational medications, the Patient confirms participation in all required monitoring and reporting activities.

13. Voluntary Consent

The Patient confirms that:

a) This Consent Form has been fully explained.

b) All questions have been answered satisfactorily.

c) No guarantees have been made regarding outcomes.

d) Consent is being given voluntarily and without coercion.

e) There has been an opportunity to discuss alternative treatments.

f) For off-label or investigational use, there has been a thorough discussion of the experimental nature of the treatment.

Patient Name (Printed): _____

Patient Signature: _____ **Date:** _____

Provider Name (Printed): _____

Provider Signature: _____ **Date:** _____

***This template is designed for general use and should be reviewed by legal counsel for compliance with state-specific requirements before implementation. The Provider should customize this form based on the specific medication being administered and relevant medical circumstances.