Twin Cities Pain Clinic

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Intrathecal Macro Dose Medication Trial

This informed consent is meant to inform you of the more common risks, consequences, complications, and precautions related to the intrathecal macro dose medication trial procedure. Upon reading this and having any questions you may have answered by your pain provider, you should be able to give informed consent to have or not to have this procedure.

I _____, have been informed of the following:

- The goals, benefits, and risks of the intrathecal macro dose medication trial.
- Alternative methods of treatment for my chronic pain.
- How the intrathecal macro dose medication trial works to control pain and expectations for relief of pain.
- Possible consequences and complications of undergoing the intrathecal macro dose medication trial.

I understand:

1. The intrathecal macro dose medication trial is a procedure used to determine if intrathecal medication will successfully reduce pain and increase function without causing side effects prior to having a Medtronic SynchroMed II pump implanted.
2. The intrathecal macro dose trial may reduce but not cure or eliminate my pain. If the trial works for me, I will experience a reduction in pain and/or an increase in function. The trial will not eliminate or cure the primary source of my pain.
3. Intrathecal medication therapy will not solve my personal or family problems because chronic pain may affect one's life and relationships with others. Sometime anxiety, depression and other effects of chronic pain occur and need to be addressed separately.
4. I have been selected as a candidate for the intrathecal macro dose pump trial because alternative therapies have not worked or are not recommended to control my pain.
5. I understand the macro dose trial procedure involves having a temporary catheter inserted into the intrathecal space.
6. During the insertion of the catheter portion of the trial, I will be positioned on my stomach, sedation may be administered as previously discussed with my provider, and the physician will use x-ray guidance to access my intrathecal space. Once, access to the intrathecal space has been obtained, the physician will insert the catheter. The catheter will be secured to my back with an adhesive dressing.
7. The FDA has approved certain medications and concentrations that are labeled for the use with the SynchroMed II Infusion system. The approved medications are Preservative-free Morphine Sulfate with a maximum concentration of 20 mg/ml; Preservative-free Baclofen injection with a maximum concentration of 2 mg/ml; Preservative –free Prialt with a maximum concentration of 100 mcg/ml; and lastly Preservative-free floxurideine or methotrexate for treatment of primary or metastatic cancer. Other medications that are NOT approved by the FDA may be used for your trial and for your treatment plan. Examples of these medications are Preservative-Free Dilaudid (hydromorphone) or Preservative-Free Fentanyl citrate. Please note that although unlikely the use of unapproved drug formulations can increase the risk of pump motor stall due to

corrosion in the SynchroMed infusion systems. The use of unapproved drugs or fluids can result in increased risks to the patient and permanent damage to the implanted pump.

8. I understand I will be under the supervision of nurses and the physician after the catheter has been inserted and while the medication is infusing. I will provide honest feedback about pain relief or side effects I am experiencing. The catheter in my back will be connected to an external pump. The nurses will periodically increase the rate of medication using the external pump.
9. I will need to be supervised for 24 hours following my trial as there may be increased risk of medication effects at 6 and 16 hours following injection of the medication. I may also experience a brief period of withdrawal following the trial as the medication level in my body drops.
10. If I experience pain relief during the trial of medication, I should not expect the same relief immediately following the implant of the pump. There will be a transition phase where the medication dose is slowly increased following surgery. **It may take weeks to months to experience the same level of pain relief I felt from the trial.**
11. I understand if my trial of intrathecal medication is successful; Twin Cities Pain Clinic will contact my insurance company to obtain prior authorization for the pump implant. If my trial is unsuccessful, the procedure may be repeated using a stronger medication dose or using a different medication. This will be discussed between my provider and me.

Potential Risks & Medication Side Effects:

Any procedure has risks and this includes the injection of medication into the intrathecal space. Any complication that can occur following anesthesia is possible, including but not limited to bleeding, infection, and even death. Common potential risks of the trial and medication side effects include the following:

- Temporary increase in pain in the days following the procedure at the injection site.
- Spinal headache resulting from a cerebral spinal fluid (CSF) leak.
- Itching
- Urinary retention
- Gastrointestinal upset
- Constipation

I hereby state that I have read and understand this document and terms of agreement. I have had the opportunity to ask my provider questions about the intrathecal macro dose trial procedure and these questions have been answered to my satisfaction. I believe I have adequate knowledge of intrathecal medication therapy and its potential risks, complications, and benefits to give my informed consent to treatment.

Patient Signature: _____ **Date:** _____