Affix Patient Label

Patient Name: Date of Birth:

Informed Consent: Skin Biopsy for Diagnosis of Small Fiber Sensory Neuropathy (SFSN)

This information is given to you so that you can make an informed decision about having **a skin biopsy for diagnosis of Small Fiber Sensory Neuropathy.**

Reason and Purpose of this Procedure:

Small Fiber Sensory Neuropathy (SFSN) is a nerve problem that affects your feeling of pain and temperature. You may have the sensation of numbness or tingling ("pins and needles") or burning or stabbing pain. Your doctor or physician assistant would like to do a skin biopsy. The doctor or physician assistant will look at nerve fibers in your skin to make a diagnosis.

The doctor or physician assistant will numb your skin and take skin samples from 3 different areas on your body (lower leg, upper thigh, and lower thigh). The skin samples will be sent to a laboratory for testing. You can expect results in about 2 weeks.

Benefits of this Procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Accurate diagnosis of your condition. This can help your doctor or physician assistant with treatment.

Risks of this Procedure:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

- **Bleeding.** Bleeding may occur during or after the biopsy. Tell the doctor if you take blood thinners. These may increase the risk of bleeding.
- **Infection.** Your doctor or physician assistant will clean your skin thoroughly before the procedure. An infection may still happen. You may need antibiotics for this.
- **Pain.** You may feel a stinging sensation when the doctor numbs your skin. This usually lasts about 5 seconds. When the medicine has taken effect, you will not feel the biopsy.
- **Scar formation.** The biopsy site is very small less than 1/8 inch. A scar may form when your skin heals. Follow your doctor's aftercare instructions to reduce your risk.

Risks Associated with Smoking:

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Associated with Obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Specific to You:

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Alternative Treatments:

Other choices:

- Do nothing. You can decide not to have the procedure.

If you Choose not to have this Treatment:

- Your doctor or physician assistant will not be able to diagnose your condition with the same degree of accuracy.

General Information:

During this procedure, the doctor may need to perform more or different procedures than I agreed to.

During the procedure, the doctor may need to do more tests or treatment.

Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.

Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.

Pictures and videos may be taken during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.

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By signing this form, I agree:

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.
- I want to have this procedure: **Skin Biopsy for Diagnosis of Small Fiber Sensory Neuropathy** ______________

  ____
- I understand that my doctor may ask a partner to do the procedure.
- I understand that other doctors, including medical residents or other staff may help with the procedure. The tasks will be based on their skill level. My doctor will supervise them.

> **Provider**: This patient may require a type and screen or type and cross prior to procedure. If so, please obtain consent for blood/products.

Patient Signature: ______________________________________ Date: __________ Time: __________

Relationship: ☐ **Patient** ☐ **Closest relative (relationship)** ____________ ☐ **Guardian/POA Healthcare**

Interpreter's Statement: I have interpreted the doctor's explanation of the consent form to the patient, a parent, closest relative or legal guardian.

Interpreter's Signature: ______________________________ ID #: __________ Date: __________ Time: __________

For Provider Use ONLY:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: ______________________________________ Date: ___________ Time: __________

Teach Back:

Patient shows understanding by stating in his or her own words:

_______ Reason(s) for the treatment/procedure: ______________________________________

_______ Area(s) of the body that will be affected: ______________________________________

_______ Benefit(s) of the procedure: ______________________________________

_______ Risk(s) of the procedure: ______________________________________

_______ Alternative(s) to the procedure: ______________________________________

OR

_______ Patient elects not to proceed: ______________________________ Date: ___________ Time: ___________

(Patient signature)

Validated/Witness: ______________________________________ Date: ___________ Time: ___________