Affix Patient Label	
Patient Name:	Date of Birth:

Informed Consent: Disc Aspiration and Biopsy

This information is given to you so that you can make an informed decision about having **a CT or fluoroscopy guided needle aspiration or biopsy of an intervertebral disc space and/or adjacent bone of an intervertebral disc space with a biopsy of nearby bone if needed.** This procedure is most often done with moderate sedation or anesthesia.

Reason and Purpose of this Procedure:

To determine if there is a disc space infection and try to make a specific diagnosis.

Disc spaces are located in between the vertebral bodies (spinal bones) in the spine. Sometimes infection can occur in the disc space and in the spinal bone next to the disc space. If an infection occurs, it is important to determine the type of infection. This will allow your doctor to use the best treatment for the infection. In some cases, degenerative disc disease or a tumor can look similar to infection. This test can help your doctor know if there is an infection or not.

The radiologist will use fluoroscopy or CT guidance to place a needle into the abnormal disc space and/or adjacent bone. Small samples of tissue or fluid will be removed through the needle and will be sent for testing.

Medication to numb your skin will be injected at the needle insertion site. You will be given some intravenous relaxing medication and pain medicine during the procedure. For most patients, the procedure is well tolerated. Some patients will have moderate discomfort during the procedure.

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.

- Help your doctor decide how to treat you.
- Diagnose the type of infection.
- Make your recovery more rapid.

General Risks of Procedures:

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.** In rare cases you may need a blood transfusion or emergency procedure to stop bleeding.
- **Infection.** Could occur in the skin, soft tissue under the skin or at the internal biopsy site. These infections are rare. You may need antibiotics.
- **Complications from sedation medicine.** You may have low blood pressure. You may have breathing problems including slow breathing and choking on vomit (aspiration). If you are sedated you will be monitored by a nurse and given oxygen to breath.

Risks of this Procedure:

- **Inconclusive results.** Even when infection is present, it is often not possible to make a specific diagnosis by a needle aspiration. The information is considered to be so important that the aspiration and biopsy is still considered to be worth performing.
- **Rare serious complications include the following**:
  - **Injury to a spinal nerve.** This could cause permanent numbness or weakness.
  - **Injury to the lining of the spinal canal.** This could result in leak of spinal fluid which could cause a headache. This could require surgery to repair. This could cause spinal meningitis.
  - **Bleeding into the spinal canal.** This could compress the spinal cord or nerves. This could require emergency surgery to drain the blood and release the compression. Paralysis or nerve damage could occur.
  - **Injury to an artery supplying the spinal cord.** This could result in paralysis.
  - **Death.**

Potential Radiation Risks:

- **Any exposure to radiation may cause a slightly higher risk for cancer later in life.** This risk is low.
- **Skin rashes.** Skin rashes may lead to breakdown of skin and possibly severe sores. This is rare.
- **Hair loss.** This does not happen to everyone. This can be temporary or permanent.
- **It is possible we may have to use higher doses of radiation.** If we do, we will tell you.
- **If you see changes with your skin, you should report them to your doctor.**

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:

- Open surgical biopsy under general anesthesia.
- Do nothing. You can decide not to have the procedure.

If you Choose not to have this Treatment:

- Your doctor may find it more difficult or not possible to effectively treat your problem.

Information on Moderate Sedation:

You will be given medicine in an IV to relax you. This medicine will also make you more comfortable. This is called “moderate sedation”. You will feel sleepy. You may even sleep through parts of your procedure. We will monitor your heart rate and your blood pressure. We will also monitor your oxygen level.

If your heart rate, blood pressure or oxygen levels fall outside the normal range, we may give medications to reverse the sedation. We may be unable to reverse the sedation. We may need to support your breathing.

Even if you have a NO CODE status:

- You may need intubation to support your breathing.
- You may need medications to support your blood pressure.

We will re-evaluate your medical treatment plan and your NO CODE status when sedation has cleared your body.

Benefits of Moderate Sedation:

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.

- Less pain during the procedure.
- Less anxiety or worry.
- Decreasing your memory of the procedure.

Risks of Moderate Sedation:

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. The list includes:

- Decreased breathing during the procedure and dropping oxygen levels. To help you breathe, a tube may be placed into the mouth or nose and into the trachea to help you breathe.
- Allergic reactions: nausea & vomiting, swelling, rash.
- Vomit material getting into the lungs.
- A drop in blood pressure. This needs fluids or medicine to increase blood pressure.
- Heart rhythm changes that may require medicines to treat.
- Not enough sedation or analgesia resulting in pain or discomfort.

Your physical and mental ability may not be back to normal right away. You should not drive or make important decisions for at least 24 hours after the procedure.

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 salespeople, 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.

Affix Patient Label	
Patient Name:	Date of Birth:

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: **Needle Biopsy of:** ______________________________

  Aspiration Biopsy Location: ______________________________
- 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**

Reason patient is unable to sign: ______________________________

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: ___________

Telephone Consent ONLY: *(One witness signature MUST be from a registered nurse (RN) or provider)*

1st Witness Signature: _____________ 2nd Witness Signature: _____________ 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: ___________