BRONSON

Affix Patient Label	
Patient Name:	Date of Birth:

Informed Consent: Liver Mass Biopsy

This information is given to you so that you can make an informed decision about having an **ultrasound or CT guided liver biopsy of a liver abnormality.** This procedure is most often done with moderate sedation or anesthesia.

Reason and Purpose of this Procedure:

Determine if the liver abnormality is benign or cancer.

A biopsy needle will be placed through the skin in the upper abdomen or between the lower ribs on the right into the liver abnormality to take small samples of tissue. These will be sent to the pathologist to examine. The radiologist will use ultrasound or computed tomography (CT) to guide placement of the needle and select the best location to biopsy. A final diagnosis will not be made at the time of the biopsy. The final result will be sent to your doctor usually within a week.

The biopsy procedure is usually not very painful. Local anesthetic will be injected and you will be given some intravenous relaxing medication and pain medicine during the procedure. Some patients have moderate pain during the biopsy.

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.

- Determine if the liver abnormality is benign or malignant and try to make a specific diagnosis.
- Help your doctor decide how to treat you.
- Decide if surgery is needed.

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.** Mild or serious bleeding can occure. This may require additional procedure or surgery
- **Infection.** Could occur in the skin, soft tissue under the skin or at the internal biopsy site. These infections are rare. Antibiotic treatment might be needed.
- **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 breathe.
- **Needle puncture of lung.** You may need a chest tube to re-inflate the lung.
- **Infection in the bloodstream.** This is treated with antibiotics and intravenous fluids. You may need further hospitalization.
- **Needle puncture of bile duct or gallbladder.** This could result in bile leaking into the abdomen. This can cause abdominal pain and may need treatment with pain medicine. In very rare cases a procedure is needed to stop the leak or drain the bile that leaked.
- **Needle puncture of bowel.** This could cause infection or require surgical repair.
- **Seeding of cancerous cells or infectious material along biopsy tract.**
- **Inconclusive results.** you may require repeat biopsy or other testing.

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.

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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:

_____

_____

_____

_____

Alternative Treatments:

Other choices:

- Undergo surgery 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 treat you.
- If you have cancer, it may become more advanced without diagnosis and treatment.
- _____

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.

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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: **Liver Mass Biopsy** _____

  _____
- 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: _____