	Affix Patient Label	
	Patient Name:	DOB:

Informed Consent Photodynamic Therapy with Levulan® and Blu-U®

This information is given to you so that you can make an informed decision about having **Photodynamic Therapy with Levulan® and Blu-U®).**

Reason and Purpose of the Procedure:

Levulan® (aminolevulinic acid 20%) is a solution used to treat pre-cancerous skin lesions (actinic keratosis). It is applied to the skin and "activated" by a special light (Blu-U®). This process is called photodynamic therapy. It is used to remove precancerous skin lesions.

Benefits of this procedure:

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

- Decrease in pre-cancerous lesions of the skin

Risks of 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.

- Discomfort
- Burning
- Swelling
- Redness and peeling. The peeling may last many days and the redness for one week. The more lesions there are the longer these reactions will last.

Risks associated with smoking:

Smoking is linked to an increased risk of infections. It can decrease healing of skin tissue. 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:
- Cryosurgery (freezing off individual lesions)
- Excision (surgically removing lesions)
- Do nothing. You can decide not to have the procedure.

If you choose not to have this treatment:

- Pre-cancerous lesions have a 10% chance of becoming a skin cancer.
- The lesions can grow larger.

General Information

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

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

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

My insurance company may not pay for this device or procedure. I know I am responsible for charges not covered by my insurance.

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: **Photodynamic Therapy (Levulan®/Blu U®)**
- 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 surgery. The tasks will be based on their skill level. My doctor will supervise them.

Patient Signature____Date:__________Time:_________

Relationship: ☐Patient/Parent of minor ☐Closest relative (relationship) ☐Guardian/POA Healthcare

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

Interpreter: ____Date___________Time__________

Interpreter (if applicable)

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 the 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: ________