CONSENT FOR CANCER RESEARCH

Project Title: PRMC-5617, Vitamin D as a Nutritional Neoadjuvant during Photodynamic Therapy of Basal Cell Carcinoma in Basal Cell Nevus Syndrome
Sponsor: National Cancer Institute (NCI), National Institutes of Health (NIH)
Principal Investigator(s): Dr. Edward Maytin, PH#216-445-6676

Cancer research studies are coordinated by physicians and scientists from Cleveland Clinic, University Hospitals and Case Western Reserve University (CWRU) through the NIH National Cancer Institute (NCI) designated Case Comprehensive Cancer Center (Case CCC). The goal of this collaboration is to enhance cancer treatment and research in Northeast Ohio. This study is being offered at Cleveland Clinic (CC).

One or more of the Investigators conducting this study serve as consultants for the company that makes products used in this study. These financial interests are within permissible limits established by the local institutional Conflict of Interest Policy. If you have any questions regarding conflicts of interest, please ask you study doctor or call the Cleveland Clinic Institutional Review Board at (216) 444-2924.

What is the usual approach to my Basal Cell Carcinoma?
In the United States, traditional treatment approaches to Basal Cell Carcinoma (BCC) involve cryosurgery with liquid nitrogen, curettage and electrodessication, or scalpel excision.

What are my other choices if I do not take part in this study?
If you decide not to take part in this study, you have other choices. For example:

- you may choose to have the usual approach described above
- you may choose to take part in a different study, if one is available
- or you may choose not to be treated for cancer. For example: comfort/palliative care

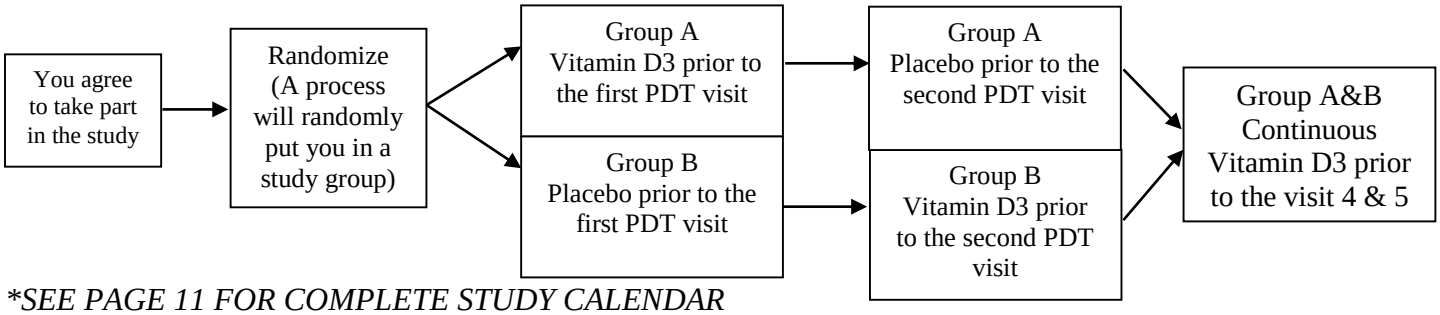
Why is this study being done?
You/your child (for this document "you" will refer to your child if the patient in the study is a child) are being invited to participate in a research study. The purpose of this trial is to study patients with multiple Basal Cell Carcinoma (BCC) who will be receiving Photodynamic Therapy (PDT) as treatment for their tumors. We want to establish what the optimal conditions are for treating BCC tumors with PDT. Previous research suggests that taking Vitamin D prior to the start of PDT could help improve the effectiveness of the treatment in eliminating the BCC. Overall, your participation in this study will help us learn whether oral Vitamin D3/PDT is effective as combination therapy for skin cancer (BCC).

Photodynamic Therapy (PDT) is an investigational (experimental) technique that works by combining a photosensitizing topical agent and an intense light source to kill tumor cells. PDT is currently approved for the treatment of BCC in Europe, Canada, and Australia. However, it is experimental in the United States because it is not approved by the Food and Drug Administration (FDA).

What are the study groups?
All people in this study have been confirmed to have had at least 3 BCC or a diagnosis of Basal Cell Nevus Syndrome (BCNS). The study will be double-blinded. Neither the patient nor the treating physicians will know which patients receive the Vitamin D3 or placebo pills. Using a "coin toss" approach, the Research Pharmacist will assign each patient to GROUP A or to GROUP B (see illustration below). GROUP A is to receive Vitamin D3 prior to their first PDT visit, and placebo prior to their second PDT visit. GROUP B will receive placebo prior to their first PDT visit, and Vitamin D3 prior to their second PDT visit. Those patients from both Group A and Group B that were found to be Vitamin D deficient, will receive Vitamin D to take prior to their third PDT visit.

A process will be used to assign you, by chance, to one of the study groups. Neither you nor your doctor can choose which group you are in. This is done by chance because no one knows if one study group is better or worse than the other.

To find out what will happen to you during this study read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



**SEE PAGE 11 FOR COMPLETE STUDY CALENDAR*

How long will I be in this study?
Overall, participation in the study will last a total of about 6 months and will include 5 in-person study visits and 4 at home phone calls. You will receive PDT treatment at 3 of these 5 in-person visits. During the 4 at home phone calls, a study nurse will call and check up on you and record side effects. No formal study follow-up is planned after completion of study participation, but you will be encouraged to return for routine examination at 6 month intervals for 2 years.

What extra tests and procedures will I have if I take part in this study?
In order to evaluate the effectiveness of this new method for treating BCC, there may be extra procedures that you will need to have if you take part in this study.

<u>Photodynamic Therapy (PDT)</u>
PDT is a noninvasive cancer treatment in which a topical agent (referred to as Levulan or ALA) is applied to the BCC and then exposed to a particular type of light. The light source used, known as Blue Light (Blue-U, 400 nm), will target and kill the cancerous cells. PDT requires multiple treatments to achieve clearance of BCC, especially for large lesions.

<u>Pharmacokinetic (PK) studies</u>
PK studies measure the amount of Vitamin D you have in your blood at various times during the

study. At each time point, about 10ml (2 teaspoons) of blood will be drawn for research purposes, including several biomarkers (genes and proteins related to your cancer).

Research biopsies

A skin biopsy is the removal of a small (pencil eraser-sized) circle of skin using a cookie cutter-like instrument. This procedure involves numbing the designated area of skin with lidocaine (similar to what dentists use) and removing a circle or "plug" of skin. Although the lidocaine can tingle or hurt briefly during the numbing process, you should not feel any pain while the punch biopsy is being obtained. The circle is then closed using the appropriate approved methods, which prevents bleeding, speeds healing, and improves the appearance. Any stitches present will be removed 7-14 days later. This procedure takes ½ to 1 hour depending on the number of biopsies taken.

Photographs

Photographs of all treated areas will be taken at four different time points during the study. These will be used to determine rates of tumor shrinkage in response to the first, second, and third PDT treatments by comparing measurements of the diameter, surface properties, and erythema of BCC lesions. The photographs will be maintained in a secure area with limited access. Safeguards are in place to protect from any inappropriate access to data including: use of codes, encrypted and/or password protected computers and phones, and limiting access to data to only the research team.

Noninvasive Fluorescence (NIF)

NIF refers to the measurement of organic compounds known as protoporphyrin IX (PpIX) and singlet oxygen ($^1O_2$). BCC sites will be measured at three different time points during the PDT treatment using two experimental devices. Each of the devices can be regarded as "fancy cameras" (light collection instruments) that use either a camera flash or a weak "classroom laser" pointer, to stimulate PpIX or $^1O_2$ so that they "glow". The "glow" is then collected by the appropriate detector. Each noninvasive device is held several inches away from the skin, never touching the patient, and is inherently safe. NIF is helpful in evaluating the success of the PDT treatment.

Important Pregnancy Testing Information for Patients Enrolling in the Study

PRIOR TO ENROLLMENT: Before we can enroll you as a participant, all females of childbearing potential will be asked to take a urine pregnancy test as a positive result will disqualify you from participation. If you are under 18 years of age, the results from the pregnancy test will be disclosed to yourself AND to your parent(s)/legal guardian.

In addition, all females of childbearing potential must agree to use a medically acceptable method of contraception during your participation in the trial. These can include: abstinence, estrogen-progestin oral contraceptive pills/patches/vaginal ring, progestin implant or injection, diaphragm with spermicide, male condom plus vaginal spermicide, surgical sterilization, intrauterine device, or vasectomy of partner or spouse (more than 6 months prior to screening/enrollment visit).

If you become pregnant at any point during the study, you must inform the study team immediately as this may disqualify you from further participation in the trial.

Before you begin the study:
You will need to have the following extra tests to find out if you can be in the study:

- Pregnancy Test (*only females of child bearing potential)
- Physical exam and documentation of at least 3 likely BCC tumors
- Biopsy and histological confirmation of at least 2 of the 3 likely BCC tumors

Biopsies may be taken for the study at your screening/baseline visit. If you have never had a biopsy confirmed diagnosis of BCC, then this procedure is required in order for you to take part in this study because the results will be used to confirm a diagnosis of BCC. For patients without any known history of BCNS but who are presenting with 3 or more possible BCC lesions, we will require that 2 lesions be confirmed as BCC through biopsy or by obtaining the biopsy report if the biopsies were performed elsewhere. The specimens will be submitted to the Pathology Department of the Cleveland Clinic for processing, and the results will be reported out by staff from the Departments of Dermatology and Pathology. Because these lesions are of potential danger to the patient and would normally require a biopsy as standard of care treatment, the costs of each biopsy will be billed to the patient's medical insurance company.

If the exams, tests, and procedures show that you can take part in the study, and you choose to participate, then you will need the following extra procedures. They are not part of the usual approach for your type of cancer.

During the study the following will be additional research procedures:

- Photodynamic Therapy (PDT) (3 treatments)
- Blood draw (5 procedures)
- Skin exam and lesion count (5 exams)
- Photography of BCC lesions (4 sessions)
- Noninvasive Fluorescence (NIF) dosimetry (2 measurements)
- Biopsy of any lesion unresponsive to PDT (1 procedure **if needed)*

What possible risks can I expect from taking part in this study?
If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss
- The study drug(s)/study approach may not be better, and could possibly be worse, than the usual approach for your cancer.
- There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with

new ways of tracing information. In some cases, this information could be used to make it harder for you to get or keep a job. There are laws against misuse of genetic information, but they may not give full protection, although the researchers believe the chance these things will happen is very small.

- There can also be a risk in finding out new genetic information about you, including health information about inherited traits that might affect you or your blood relatives. However, note that the genes that Dr. Maytin plans to examine in your DNA are limited to those affecting your response to Vitamin D and to PDT, and not to any known genetic disease.

The Vitamin D3 used in this study is a natural vitamin (cholecalciferol; VD3) that affects how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood to determine the level of VD3 in your body 5 times during the study. You will be asked to take 10,000 units of VD3 or a placebo for a period of 5 or 14 days prior to your PDT treatments; this amount has been shown to be very safe when taken for a limited time as in this study. You will also be receiving topical Levulan and activation with light (PDT). Side effects of VD3, and of PDT, are described in more detail below. As with all treatments, there is always some risk that you could have side effects from the study drug(s)/study approach.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the doctor if you are at risk for hypercalcemia (renal disease, sarcoidosis, etc.)
- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust medications or some other aspects of the treatments to try to reduce side effects.

Potential Risk or Discomfort from Research Procedures

Photodynamic Therapy (PDT)

Stinging/burning pain at the illumination site is the most common symptom reported during and after receiving blue light treatment. Other adverse effects may include redness, swelling, crusting, itchiness, peeling and blisters, and skin infections. Pain occurring during treatment will be controlled via cooling of the skin using ice cloths, and/or a Syneron chiller (refrigerated air). Additional standard aftercare measures will be provided, including a soothing lidocaine-containing ointment known as triamcinolone ointment. It is very rare, but you could have an allergic reaction to the lidocaine that is used to numb your skin. Tell your research team if you are allergic to any drugs in the "-caine" family (for example lidocaine, Novocaine). An allergic reaction can be severe and life threatening.

You will receive detailed post-treatment instructions to avoid sun exposure. A questionnaire will be provided for patients to take home and record any potential side effects.

ALA is a natural component found in all cells in the human body. The prodrug, Levulan, is a liquid preparation with a fixed concentration of 20% aminolevulinic acid (ALA) that is delivered topically as a uniform film that dries upon application to the skin. The application of Levulan is not associated with any risks or side effects.

Vitamin D

Cholecalciferol (Vitamin D3) is not a drug. However, there is some evidence of a link between patients who take Cholecalciferol and developing hypercalcemia. Hypercalcemia is a condition in which you have too high a concentration of calcium in your blood. Symptoms of hypercalcemia range from mild to severe. They may include increased thirst and urination, belly pain, nausea, bone pain, muscle weakness, confusion, fatigue, and in rare cases even death. Therefore, if you are at risk for hypercalcemia (renal disease, sarcoidosis, etc), you will not be permitted to participate in the study.

Skin Biopsy

A skin biopsy is a procedure in which a sample of skin tissue is removed, processed, and examined under a microscope. Several different methods may be used to obtain the sample, depending on the size and location of the abnormal area of skin. Risks associated with biopsies include pain, redness, swelling, low blood pressure, excessive bleeding, bruising, or draining at the needle site, abnormal wound healing, fever, infection, and allergic reaction to the medication used to numb the skin over the biopsy site. Infection is very rare as your skin is cleansed with an antiseptic solution and the instruments used are sterile.

Blood Draw

The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples do not cause any serious problems; however, this may cause bleeding, bruising, discomfort, infections, dizziness, or fainting.

Genetic Testing

Note that we will be collecting your DNA to specifically test for normal variants in genes related to Vitamin D and thymidine metabolism, neither of which are associated with any known inheritable diseases. Risks of being in genetic testing include the misuse of personal, genetic information. All personnel who will have access to genetic information about you are ethically and legally obligated to maintain the confidence of that information. Although rare, misuse of such information has caused problems for persons related to their employment and/or their life and/or health insurance and other benefits or entitlements. However, it is still important for you to know that additional safeguards against improper use of your genetic information are in place, as follows:

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), effective May 21, 2010, generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Reproductive Risks

If you are pregnant or nursing at the time of study participation, you cannot be in this study. You should not get pregnant, breastfeed, or father a baby while in this study. The Photodynamic Therapy used in this study could be very damaging to an unborn baby. The effects of 5-aminolevulinic acid (Levulan™) on the developing human fetus are unknown. It is unknown what effects systemic exposure to ALA might have on fertility or reproductive function. For these reasons, women of childbearing age should check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study.

Loss of Confidentiality

There is also the possibility for loss of confidentiality. Every effort will be made to maintain the privacy and confidentiality of your information (data) during the study. You will be assigned a study code and all clinical data required by the protocol will be identified using that code. All data is stored using a unique subject assigned number and no personal identifying data will be entered. Members of the Cleveland Clinic and Case Comprehensive Cancer Center will have access to your data.

What possible benefits can I expect from taking part in this study?

We cannot know if you will have any benefit as a result of your participation in the study; it is possible the study treatment may improve your cancer, which may give you relief from some symptoms, improve your quality of life or prolong your survival. However, it is possible that your condition could worsen. Your participation in this study will help us to obtain information about treating subjects with a new combination therapy of oral Vitamin D3/PDT as a treatment for skin cancer (BCC).

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest

- If new information becomes available
- If you do not follow the study requirements
- If the study is stopped by the sponsor, Institutional Review Board (IRB) or FDA.

What are my rights in this study?
Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

What are the costs of taking part in this study?
Your involvement in this research study is voluntary and you will not be paid for your participation. However, you will receive a free parking voucher and a stipend in the amount of $200.00, per clinic visit. The study coordinator will provide you with the parking voucher on the day of your clinic visit, but the stipend(s) will be mailed to you shortly thereafter.

The IRS requires CCF to report payments to an individual of $600 or greater (in a calendar year) on a Form 1099-MISC. Your name, address and social security number will be collected to track the payments made to you and, if you receive $600 or greater, will be used to process a Form 1099-MISC.

The study agent, Photodynamic Therapy (PDT) and Vitamin D3, will be provided free of charge by National Cancer Institute (NCI) and National Institutes of Health (NIH) while you are participating in this study. Neither you nor your insurance provider will be responsible for the costs of any research-only tests or procedures. The blood work for research purposes will not be charged to you. It will be paid for by the research study.

You and/or your health plan/insurance company will need to pay for some or all of the costs of treating your cancer in this study (i.e., medical history, review of medications, physical exams, biopsies, routine blood tests, pregnancy test, x-rays and/or scans for tumor measurement). Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://www.cancer.gov/clinicaltrials/learningabout.

What happens if I am injured or hurt because I took part in this study?
If you believe that you are injured as a result of the research procedures being performed, please immediately contact the study doctor. If injury occurs as a result of your involvement in this research, medical treatment is available from Cleveland Clinic or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions. Further information about research-related injuries

is available by contacting the Clinic Institutional Review Board at (216) 444-2924.

HIPAA AUTHORIZATION
Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you volunteer to participate in this research, your protected health information (PHI) that identifies you will be used or disclosed to Dr. Edward Maytin MD, and the research study staff at Cleveland Clinic for the purposes of this research and to Case Western Reserve University for administration.

The PHI that we may use or disclose (release) for this research may include your name, address, phone number, date of birth, Social Security number, information from your medical record, lab tests, or certain information relating to your health or condition.

Some of the tests and procedures done solely for this research study may also be placed in your medical record so other doctors know you are in this study. Upon completion of the study, you may have access to the research information that is contained in your medical record.

In addition to the investigators and research staff listed above, your PHI may be looked at by other groups involved with the study such as the Cleveland Clinic Institutional Review Board and the Case Comprehensive Cancer Center Protocol Review and Monitoring Committee. Your PHI may also be used by and/or disclosed (released) to:

- NCI and NIH, its study monitors and representatives
- NCI & NIH collaborators and licensees
- Case Comprehensive Cancer Center members and collaborators
- The Food and Drug Administration;
- The Department of Health and Human Services;
- The National Cancer Institute (NCI);
- Medocity Inc (only for patients who opt in)
- Other Institutional Review Boards;
- Data Safety and Monitoring Boards;

Once your personal health information is released it may be re-disclosed and no longer protected by privacy laws.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to:

Dr. Edward Maytin, MD
Case Comprehensive Cancer Center
Cleveland Clinic
9500 Euclid Ave.
Cleveland, OH 44195

Your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of this research. Also, information already disclosed outside the Cleveland Clinic cannot be retrieved. This will not affect your rights to treatment or benefits outside the research study.

The Cleveland Clinic will not use your information collected in this study for another research purpose without your written permission; unless the Cleveland Clinic Institutional Review Board (IRB) assures your privacy and confidentiality is protected. The IRB is a committee whose job it is to protect the safety and welfare of research subjects.

By signing this informed consent form, you are authorizing such access to your research and medical record information. If you choose not to sign this consent form, you will not be able to participate in this research study. This Authorization does not have an expiration date.

Voluntary Participation
Your participation in this research study is voluntary. Choosing not to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed.

In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating.

Questions about the Research
If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact Dr. Edward Maytin, Department of Dermatology at 216-444-5139.

Cleveland Clinic Foundation Clinical Research Unit (CRU) study participants may also contact the CRU Research Subject Advocate (RSA), at 216-445-7846 with regard to questions about study participation and research subject protections.

After hours, you should contact the page operator at (216) 444-2200 or toll free at (800) 223-2273, and ask for the dermatologist on call.

Where Can I Get More Information?
If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about: concerns regarding the study, research participant's rights; research-related injury; or other human subjects issues, you may contact the Institutional Review Board (IRB) at Cleveland Clinic IRB 216-444-2924.

You may call the National Cancer Institute's Cancer Information Service at:
1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/

- For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
- For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

You will get a copy of this form. If you want more information about this study, ask your study doctor.

US National Institutes of Health (NIH) Clinical Trial Database:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, if applicable, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Communication during the study by smartphone, i-Pad, or home computer

In this study, we are using an innovative way to help identify and communicate with patients through their smart phones or home computers, to make communication easier and more reliable. To develop this service, Dr. Maytin's team worked with a software developer called Medocity, Inc., whose online platform has been configured to help guide each patient's journey through the clinical trial from beginning to end. This includes scheduling of visits, routine questions and answers during the study, and online reminders about when to take the study medications or record your symptoms. This is not meant to completely replace telephone calls, which will always be an option, but instead is designed to make communication more reliable and to insure that no information is lost. A particular advantage of the digital platform is its broad versatility, since it is compatible with all smart phones (Apple or Android) and with all desktop-based computers (PC and Mac). It also provides a way for study patients to securely upload photographs and biopsy reports. Information on the web platform is encrypted and secure, and the system has been approved by the Cybersecurity GRC (risk and compliance committee) of the Cleveland Clinic.

PLEASE CHOOSE ONE OF THE FOLLOWING OPTIONS:

☐ YES, I agree to use phone/web-based communication during the clinical study. I understand that there is a one-time sign-up procedure in which I will enter my name, E-mail address, phone contact, and a few targeted health questions on the Medocity sign-up page. The Study Coordinator will give me with a personal training session with all the details about how to use the website.

☐ NO, I do not want to do any electronic or text messaging, and will instead rely on standard telephone and mail for communication.

Signature
Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

Signature of Participant	Date	Printed Name of Participant

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

Signature of Person Obtaining Consent	Date

Printed Name of Person Obtaining Consent

Permission of Parent/Legal Guardian (If child less than 18 or Legally Incompetent Adult)
You and your child have had the above research study explained to you and your child in language that you and your child can understand, and you give permission for your child's participation.

Parent/Guardian Signature	Date

Printed name of Parent/Guardian	Relationship to child

Children who are Below 18 Years of Age or a Legally Incompetent Adult
I have had the above research study explained to me in language that I can understand and I agree to participate.

Signature of Participant or Child	Date

Printed Name of Participant or Child

Timeline of Procedures for Patients Enrolled in the Study

STUDY CALENDAR

		Visit 1 Screening & Enrollment	Phone Call	Visit 2 PDT 1	Phone Call	Visit 3 PDT 2	Phone Call	Visit 4 PDT 3	Phone Call	Visit 5 End of Study
2	Review of Previous Clinical Records Including Biopsy Reports if Available	X								
1	Skin Exam & Lesion Counts with photography	X		X		X		X		X
2	Skin Biopsy of 2 Lesions (*if not confirmed previously)*	X *								
3	Blood Draw	X		X		X		X		X
4	Dispense Study Medication (Vitamin D3 or Placebo)	X		X		X				
5	Dispense Patient Take Home Study Medication Journal	X		X		X		X		
6	Dispense Patient Take Home Side Effects Journal			X		X		X		
10	Call Patient to follow up and record side effects				X		X		X	
7	Call Patient and Provide Study Medication Instructions		X		X		X			
8	Photodynamic Therapy (PDT) & Levulan Application			X		X		X		
9	Noninvasive Fluorescence dosimeter (#)			X *		X *		X *		
11	Dispense Patient Satisfaction Questionnaire									X
12	Biopsy of Any Lesion Unresponsive to PDT *(if needed)*									X *

**if needed*