Institutional Review Board
Human Research Protections
Protocol Narrative ~ Expedited/Full Committee Biomedical/Clinical Research
Version 2015

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Lead Researcher Name: Kristen Kelly	
Study Title: Skin Imaging to Inform Laser Treatments	

CLINICAL TRIAL MASTER PROTOCOL AND INVESTIGATIONAL BROCHURE INFORMATION *

	Master Protocol	**Investigator Brochure:** <Specify Drug/Device>	**Investigator Brochure:** <Specify Drug/Device>	**Sponsor Consent Form Template(s)**
Version #:				
Version Date:				

[X] This study is investigator-authored (investigator developed the study and is conducting the study at UCI and/or with other non-UCI sites).

* Add columns as applicable

NON-TECHNICAL SUMMARY

Provide a brief non-technical summary or synopsis of the study that can be understood by IRB members with varied research backgrounds, including non-scientists and non-affiliated members.

The purpose of this study is to obtain information (such as lesion depth, depth of the most superficial part of the lesion, and the size and density of blood vessels) with the assistance of an imaging device, and use this information to assist in selection of laser settings for the treatment of skin conditions. The imaging modality is called Optical Coherence Tomography (OCT). Multiple laser modalities will be used including intense pulsed light (BroadBand Light, Profractional Sciton), pulsed dye laser (Vbeam Perfecta , Candela), long-pulse 755nm (GentleLASE, Candela), Sciton long-pulse 1064nm lasers, and non-ablative and ablative fractional resurfacing (Profractional, Sciton) lasers. All of the lasers noted above are the only ones that will be used in this study; they have 510k clearance and are being used as per their approved indications in this study. The choice of laser type is based on the skin lesion and is recommended by the physician, and subjects who are going to enroll in this study will already be planned to undergo laser treatment as a standard of care for their condition. This is a pilot study that will explore the utility of skin imaging in guiding the laser treatment of skin lesions.

SECTION 1: PURPOSE AND BACKGROUND OF THE RESEARCH

Provide the scientific or scholarly rationale for the research. Describe the relevant background information and the specific gaps in current knowledge that this study intends to address.

The purpose of this research is to assist laser treatment of skin conditions by imaging the skin to obtain information about lesional skin. This is a pilot study that will explore the utility of skin imaging in guiding the laser treatment of skin lesions. This study will utilize Optical Coherence Tomography (OCT). Data acquisition of the skin will guide laser treatment by providing information on skin lesion characteristics.

There have been shown to be many applications for OCT. This imaging modality have been used to examine normal skin, burn scars, hemangiomas, nevus flammeus, fibrosarcomas, rosacea, and telangiectasias[1-12]. Skin conditions to be studied include vascular lesions, scars, and inflammatory conditions. Normal and lesional skin will be assessed.

Currently, laser settings are selected without the assistance of imaging. Imaging with OCT provides more information about the characteristics of the skin lesion (such as lesion depth, depth of the most superficial part of the lesion, and the size and density of blood vessels), which could allow for more informed selection of laser settings to treat individual skin lesions. OCT has been used to examine laser treatments as well, but our proposed protocol would include the use of OCT to examine the stated skin lesions above before and after laser treatment in order to compare to prospective controls that did not undergo OCT imaging. The goal of our study is to optimize laser treatment with the assistance of OCT and guide future laser treatments[13-15]. It has been shown that very early treatment of vascular lesions such as Port-Wine birthmark during infancy most often results in a better chance of lesion regression and can greatly improve the clinical and psychosocial well-being of the patient.[16,17] Therefore, we will utilize OCT imaging, which is FDA-cleared for use on subjects of all ages to image our patient population.

The following imaging modalities will be used:

1) **Optical Coherence Tomography (OCT):**
OCT is an imaging modality that uses light to image turbid media such as living tissues, and has been successfully used to generate high resolution (~10 micron) cross-sectional images of tissue microstructure in the human retina, skin, gastrointestinal tract, and genitourinary tract[10,6]. OCT systems are now commercially available for ophthalmic and dermatologic use, and several clinical reports on the use of OCT in the vascular system and aero digestive tract (HS#2003-3025), Ophthalmology (HS#2004-3555), Pleural disorder (HS#2006-4982), Neural tissue (HS#2005-4775), Aneurysm healing (HS#2006-5031) and Oral Pathology (HS#2002-2805). This device focuses low power non-laser broad band infrared light onto tissue and does not involve input of significant amounts of energy into the subject; no temperature rise occurs. Because the wavelength of light used for imaging does not have adverse tissue effects, there is no risk.

Imaging with OCT provides information about the characteristics of the skin lesion (such as lesion depth, depth of the most superficial part of the lesion, and the size and density of blood vessels). OCT poses no known risks to the patients.

A multitude of studies have been conducted that validate the utility of OCT in imaging many types of skin lesions. Vascular lesions formulate a good portion of skin diseases studied by OCT, which includes rosacea, port-wine stain, hemangiomas, fibrosarcomas, cherry angiomas, and

telangiectasias[1,2,4-6,9,10]. Other studies have examined imaging of burn scars, the micro-circulation of the skin, and vascular changes with topical medical application[3,7,8,11,12]. In all of these studies, OCT imaging aided treatment, as well as provided a method to assess treatment outcome.

For port-wine stains, OCT has provided information such as vessel diameter and depth, which was discovered to be quite variable in PWS, indicating that tailored laser treatments are likely to improve result[1,6]. Byers et al. noted that OCT was a robust, and non-invasive method for observing longitudinal dynamics of the subcutaneous microcirculation of tumors[4]. Telangiectasias are a prominent feature of rosacea, and OCT has elucidated information about their treatment with intense-pulsed light to simply examine the effect of the treatment on the targeted lesions[10].

Provide relevant preliminary data (animal and/or human).

Multiple centers in the US and Europe have started using OCT to provide information about the skin. The PI participated in one study where information was gathered[1].

This information is not yet being used commonly to guide laser treatments.

Describe the purpose, specific aims or objectives. Specify the hypotheses or research questions to be studied.

The purpose of this research is to assist laser treatment of skin conditions by imaging the skin to obtain information about lesional skin. This is a pilot study that will explore the utility of skin imaging in guiding the laser treatment of skin lesions. The current standard of laser treatment without the assistance of imaging is to treat patients based on qualitative, visual characteristics of the skin lesion, such as vascularity, pliability, height, and pigmentation of the lesion. Imaging with OCT provides more information about the characteristics of the skin lesion (such as lesion depth, depth of the most superficial part of the lesion, and the size and density of blood vessels), allowing for more precise adjustment of laser settings to treat individual skin lesions. Laser treatment will be used within the approved normal parameters consistent with the standard of care. Our hypothesis is that treatments with the assistance of the OCT device will exhibit improvement of their lesions with few side effects.

Describe the primary outcome variable(s), secondary outcome variables, and predictors and/or comparison groups as appropriate for the stated study objectives/specific aims.

Primary outcome variables include assessment of photograph improvement. Two board certified dermatologists will grade the degree of improvement (clearance of the lesion) in quartiles (no clearance=0-25, mild clearance=26-50, good clearance=51-75, excellent clearance=76-95, complete clearance=96-100).
Secondary outcome variables: repeat measurements with OCT, including lesion thickness, size, size of blood vessels, and density of blood vessels, and number of superficial blood vessels.

List up to ten relevant references/articles to support the rationale for the research. Do not append an extensive NIH-grant-style bibliography.

1. Waibel J, Homes J, Rudnick A, Woods D, Kelly KM. Angiographic optical coherence tomography imaging of hemangiomas and port wine birthmarks. Lasers Surgery Medicine 2018. PMID: 29566276.

2. Christman M.P., Feng H., Holmes, J., Geronemus R.G.,Treating Challenging Cutaneous Capillary Malformations With a 595 Nm Laser Aided By Dynamic Optical Coherence Tomography. Retrieved from American Society for Laser Medicine and Surgery Abstracts 2019.
3. Waibel A, Rudnick AC, Wulkan AJ, Holmes JD, The Diagnostic Role of OCT in Measuring the Depth of Burn and Traumatic Scars for More Accurate Laser Dosimetry: A pilot Study, J Drugs in Derm.2016. Nov;15(11)
4. Byers RA, Fisher M, Brown NJ, Tozer GM, Matcher SJ. Vascular patterning of subcutaneous mouse fibrosarcomas expressing individual VEGF isoforms can be differentiated using angiographic optical coherence tomography. Biomedical optics express. 2017 Oct 1;8(10):4551-67
5. Aldahan, A.S., Chen, L.L., Tsatalis, J.P. and Grichnik, J.M., 2017. Optical Coherence Tomography Visualization of a Port-Wine Stain in a Patient With Sturge–Weber Syndrome. Dermatologic Surgery, 43(6), pp.889-891.
6. Aldahan AS, Mlacker S, Shah VV, Chen LL, Nouri K, Grichnik JM. Utilization of Optical Coherence Tomography in the Evaluation of Cherry Hemangiomas. Journal of drugs in dermatology: JDD. 2016 Jun;15(6):713-4.
7. Themstrup L, Welzel J, Ciardo S, Kaestle R, Ulrich M, Holmes J, Whitehead R, Sattler EC, Kindermann N, Pellacani G, Jemec GB. Validation of Dynamic optical coherence tomography for non-invasive, in vivo microcirculation imaging of the skin. Microvascular research. 2016 May 25.
8. Themstrup L, Ciardo S, Manfredi M, Ulrich M, Pellacani G, Welzel J, Jemec GB. In vivo, micro- morphological vascular changes induced by topical brimonidine studied by Dynamic optical coherence tomography. Journal of the European Academy of Dermatology and Venereology. 2016 Feb 1.
9. Urban, J., Siripunvarapon, A.H., Meekings, A., Kalowitz, A. and Markowitz, O., 2014. Optical coherence tomography imaging of erythematotelangiectatic rosacea during treatment with brimonidine topical gel 0.33%: a potential method for treatment outcome assessment. Journal of drugs in dermatology: JDD, 13(7), pp.821-826.
10. Ring, H.C., Mogensen, M., Banzhaf, C., Themstrup, L. and Jemec, G.B., 2013. Optical coherence tomography imaging of telangiectasias during intense pulsed light treatment: a potential tool for rapid outcome assessment. Archives of dermatological research, 305(4), pp.299-303
11. Matcher, S.J. and Byers, R., 2014. Optical coherence tomography measurements of biological fluid flows with picolitre spatial localization.
12. Bazant-Hegemark, F., Woods, D., Hattersley, S. and Holmes, J., 2010, February. Multi-beam resolution video-rate sweptsource optical coherence tomography (OCT) provides endogenous contrast for in vivo blood flow independent of flow direction. In Proc. SPIE (Vol. 7554, p. 75542Z).
13. Mogensen M, Bojesen S, Israelsen NM, Maria M, Jensen M, Podoleanu A, Bang O, Haedersdal M. Two optical coherence tomography systems detect topical gold nanoshells in hair follicles, sweat ducts and measure epidermis. Journal of biophotonics. 2018 Apr 2:e201700348.
14. Banzhaf, C.A., Thaysen-Petersen, D., Bay, C., Philipsen, P.A., Mogensen, M., Prow, T. and Haedersdal, M., 2017. Fractional laser-assisted drug uptake: Impact of time-related

topical application to achieve enhanced delivery. Lasers in surgery and medicine, 49(4), pp.348-354.
15. Olesen UH, Mogensen M, Haedersdal M. Vehicle type affects filling of fractional laser-ablated channels imaged by optical coherence tomography. Lasers in medical science. 2017 Apr 1;32(3):679-84.
16. Troilius A, Wrangsjö B, Ljunggren B. Potential psychological benefits from early treatment of port-wine stains in children. The British Journal of Dermatology. 1998 Jul;139(1):59-65. DOI: 10.1046/j.1365-2133.1998.02314.x.
17. Sabeti S, Ball KL, Burkhart C, Eichenfield L, Fernandez Faith E, Frieden IJ, Geronemus R, Gupta D, Krakowski AC, Levy ML, Metry D, Nelson JS, Tollefson MM, Kelly KM. Consensus Statement for the Management and Treatment of Port-Wine Birthmarks in Sturge-Weber Syndrome. JAMA Dermatol. 2021 Jan 1;157(1):98-104. doi: 10.1001/jamadermatol.2020.4226. PMID: 33175124.

SECTION 2: ROLES AND EXPERTISE OF THE STUDY TEAM

List all research team members who will interact or intervene with human subjects or will have access to identifiable private information about human subjects. *Include additional rows for Co-researchers and Research Personnel, as needed.*
For each research team member, indicate all applicable research activities the individual will perform. *Finalizing informed consent is reviewing, answering/asking questions, confirming competency, as necessary, and signing/confirming the informed consent.*
If applicable, list the Faculty Sponsor as a Co-Researcher who will have research oversight responsibilities.

Lead Researcher:
Name and Degree: **Kristen M Kelly, MD**
Position/Title and Department: Clinical Professor in the Department of Dermatology at the University of California, Irvine.
Team Member will: **[X]** Screen/Recruit **[X]** Finalize Informed Consent
[X] Perform Research Activities *(describe below)* **[X]** Access subject identifiable data
List the research activities/procedures to be performed and the individual's relevant qualifications (training, experience): She will oversee all aspects of this study including developing the protocol, recruiting subjects, recording results and side effects, analyzing data, and publishing results. She will perform periodic safety reviews, quality assurance reviews of the charts and data, and reviews of protocol compliance. Dr. Kelly is a board-certified dermatologist with two years of additional training in light-based therapeutics as the Packard fellow at the Beckman Laser Institute. She is current a Professor in the Department of Dermatology at the University of California, Irvine. She will have access to subject PHI and medical record.

Co-Researcher:
Name and Degree: **John S. Soliman, MS**
Position/Title and Department: Medical Student at UCI School of Medicine, Junior Specialist in Department of Dermatology (Start Date: July 01, 2021)
Team Member will: **[X]** Screen/Recruit **[ ]** Finalize Informed Consent
[X] Perform Research Activities *(describe below)* **[X]** Access subject identifiable data

Johnis third year medical student and as of July 01, 2021 will bea full-time researcher at the University of California, Irvine, toconduct research in dermatology. He will be involved in most responsibilities for this project, such as examining patients, collecting, analyzing, and interpreting data, and publishing results. He will have access to PHI and medical records.

Co-Researcher:

Name and Degree **Christopher Zachary, MD**

Position/Title and Department: Professor and Chair of the UCI Department of Dermatology

Team Member will: **[X]** Screen/Recruit **[X]** Finalize Informed Consent

[X] Perform Research Activities *(describe below)* **[X]** Access subject identifiable data

He is a specialist in skin disorders, Mohs surgery, dermatologic, reconstructive surgery, laser surgery.

Dr. Zachary will participate in all aspects of this study, including recruiting and consenting subjects, recording results and side effects, data interpretation and publishing results. He will have access to subject PHI and medical record.

Co-Researcher:

Name and Degree: **Mihaela Balu PhD**

Position/Title and Department: Assistant Professor, Beckman Laser Institute

Team Member will: **[X]** Screen/Recruit **[ ]** Finalize Informed Consent

[X] Perform Research Activities *(describe below)* **[X]** Access subject identifiable data

She is focused on the development and application of non-invasive imaging techniques at the Beckman Laser Institute. Dr. Balu will be screening and recruiting patients for this study and assisting with collecting, analyzing, and interpreting data, and publishing results. She will have access to subject identifiable data and is participating in data analysis.

Co-Researcher:

Name and Degree: **Patrick Lee MD**

Position/Title and Department: Professor, Director of Clinical Operations, Director of Dermatologic Surgery, Department of Dermatology

Team Member will: **[X]** Screen/Recruit **[X]** Finalize Informed Consent

[X] Perform Research Activities *(describe below)* **[X]** Access subject identifiable data

Dr. Lee is board certified in dermatology and dermatologic surgery. Dr. Lee is going to have access to all data and will be involved in direct patient recruitment during regular clinical duties, informed consent process, and research procedures. He will have access to subject identifiable data.

Name and Degree: **Linda Doan MD**

Position/Title and Department: Assistant Professor, Director of Dermatopathology

Team Member will: **[X]** Screen/Recruit **[X]** Finalize Informed Consent

[X] Perform Research Activities *(describe below)* **[X]** Access subject identifiable data

Dr. Doan is board certified in dermatology and dermatopathology. Dr. Doan is going to have access to all data and will be involved in direct patient recruitment during regular clinical duties, informed consent process, and research procedures. She will have access to subject identifiable data.

Name and Degree: **Erica Baugh, BA**

Position/Title and Department: Jr. Specialist

Team Member will: **[X]** Screen/Recruit **[ ]** Finalize Informed Consent

[X] Perform Research Activities *(describe below)* **[X]** Access subject identifiable data

Erica is a full-time researcher at the University of California, Irvine, and is conducting research in dermatology. She will be involved in most responsibilities for this project, such as examining patients, collecting, analyzing, and interpreting data, and publishing results. She will have access to PHI and medical records.

Research Personnel:

Name and Degree: **Hanna Kim, MA**

Position/Title and Department:

Team Member will: **[ ]** Screen/Recruit **[ ]** Finalize Informed Consent
[X] Perform Research Activities *(describe below)* **[X]** Access subject identifiable data
Ms. Kim is the Clinical Research Administrator at the Beckman Laser Institute and Medical Clinic. Ms. Kim manages institutional review board (IRB) protocol preparation, tracking, and renewal issues. She will be responsible for protocol oversight, maintaining case record forms, and documenting our progress with the study. She will have access to subject identifiable data and patient medical records.

SECTION 3: SUBJECT POPULATION(S) (INDIVIDUALS/RECORDS/SPECIMENS)

1. Subjects To Be Enrolled on this UCI protocol (Persons/Records/Biospecimens)

1. Complete the table of subject enrollments below. *Include additional rows for subject category/group, as needed.*
2. If the study involves the use of existing records or biological specimens, specify the maximum number to be reviewed/collected and the number needed to address the research question.

Category/Group (e.g., adults, controls, parents, children)	**Age Range** (e.g., 7-12, 13–17, adults)	**Maximum Number to be Consented or Reviewed/Collected** (include withdrawals and screen failures)	**Number Expected to Complete the Study *or Needed to Address the Research Question***
Study Group	All ages	30	17
Control group (prospective controls)	All ages	30	17
		Total: 60	

3. **Overall Study Sample Size**

If this is a multi-site study, provide the total number of subjects to be enrolled from all sites.

[X] Not applicable: This study will only take place at UCI, and does not involve other sites. Total number of subjects across all sites.

A. SCREENING AND DETERMINING ELIGIBILITY

1. Indicate the **methods** for **obtaining information or biospecimens** for the **purpose of screening, recruiting, or determining eligibility** of prospective subjects. *Note: The screening activity is performed without the informed consent of the prospective subject or legally authorized representative (LAR).*
2. *UCI contact guidelines:*
   a. *Directly communicate with the potential subject; do not leave a voicemail/message.*
   b. *Only 5 attempts to contact the potential subject permitted.*
   c. *Study team member contacting potential subject must be knowledgeable and able to answer questions related to the screening and the main study.*

[ ] Not applicable: Information and/or biospecimens will not be obtained for the purpose of screening, recruiting, or determining eligibility of prospective subjects. *Skip to Section 4.*

[X] Study team will obtain information through **oral or written communication** with the prospective subject or LAR.

The recruitment script is an oral script and is actually written on the final page of this addendum. In order to avoid undue influence upon the subject, we will make it clear that participation in this study is completely voluntary, and that they may withdraw at any time.

Submit recruitment script for IRB approval. In addition to the minimum recruitment requirements, the recruitment script must include:

- ✓ *for telephone contact, the script must address when someone other than the potential subject answers the phone*
- ✓ *a description of the screening information and/or biospecimens that will be obtained*
- ✓ *the reasons for performing the screening tests*
- ✓ *what will happen to the information and/or biospecimens, if the potential subject is not eligible to participate in the study*

[X] Study team will **screen medical records** to determine subject eligibility.

Complete Appendix T to request a partial waiver of HIPAA Authorization.

[ ] Study team will **screen non-medical records** (i.e., student records) to which they have access to determine subject eligibility. Specify: <Type here>

[ ] For research accessing student records, check here to confirm that evidence of FERPA[1] compliance has been / will be obtained (and on file) from the local school/district site prior to the initiation of research.

[ ] Study team will **access stored identifiable biospecimens**.

3. For studies that will **screen medical records**, explain how the study team will access the clinical data. *Access to UCI Medical Center medical records for research purposes outside the capacity of the Honest Broker Services, such as access to physician notes, must be obtained from the Health Information Management Services.*

[1] *34 CRF 99: Family Educational Rights and Privacy Act (FERPA) applies to this research.*

[ ] Not applicable: This study does not involve the screening of medical records.

How Obtained: Indicate <u>all</u> that apply:

[ ] The study team will request specific patient information/data from UCIMC Health Information Management Services.

[X] The study team will review their UCI patients' records and abstract data directly from those records.

[ ] The study team will request specific patient information/data from UCI Health Honest Broker Services. Describe the following:

Cohort selection criteria (e.g., use the available Clinical Terms from the Cohort Discovery Tool such as Demographics: Gender, Diagnoses: Asthma, Procedures: Operations on digestive system): <Type here>

Expected cohort size/patient count: <Type here>

Cohort attributes or data elements (e.g., lab test values, medication, etc.): <Type here>

[ ] The study team will review non-UCI Health records and abstract data directly from those records. Describe the following:

Specify the non-UCI Health records that will be screened: <Type here>

Explain how the study team has access to this clinical data: <Type here>

[ ] Other; explain: <Type here>

1. For studies that will screen existing biospecimens:
   a. Indicate the source of the specimens and explain how the existing specimens will be obtained.
   b. Indicate whether the specimens were originally collected for research purposes.

[X] Not applicable: This study does not screen existing biological specimens.

How Obtained: Indicate <u>all</u> that apply:
[ ] UCI Health Pathology Biorepository

[ ] Other UCI-Health Entity; specify: <Type here>

[ ] Non-UCI Entity; specify: <Type here>

[ ] Other; explain: <Type here>

Originally collected for research purposes:
[ ] NO – Please explain: <Type here>

[ ] YES – UCI IRB approval granted under IRB protocol number (i.e. HS#): <Type here>

[ ] YES – Non-UCI IRB approval granted. Confirm **<u>one</u>** of the following:

[ ] A copy of the IRB Approval Notice and Consent Form for the original research collection will be submitted with the IRB application (APP). The IRB Approved Consent Form does not preclude the proposed activity.

[ ] A copy of the commercial Vendor Policy or a Letter from the Vendor attesting that the information was collected and will be shared in an appropriate and ethical manner will be submitted with the APP. The vendor's policy does not preclude the proposed activity.

5. Provide a complete list of the **data points, variables, and/or information** that will be collected **during the screening process** (i.e. data abstraction form). *Note: Only the minimum information necessary to determine subject eligibility should be collected during the screening process.*

For the experimental group, we would screen for the patient's age, type of lesion/diagnosis, location of the lesion, and the patient's willingness and ability to participate in the study.
For the control group, we would screen for the patient's age, type of lesion/diagnosis, location of the lesion, and the clearance of the lesion and response to treatment.
[ ] Check here if the list is submitted as a separate document with the application.

6. Specify what will happen to the information and/or biospecimens, if the potential subject is not eligible to participate in the study. *Note: Information or biospecimens of non-eligible subjects, may <u>not</u> be included as part of data analysis or disclosed beyond the study.*

[ ] The study team plans to destroy the identifiable information and/or biospecimens at the earliest opportunity consistent with conduct of the research. Describe the protocol specific plan and timeframe for destruction: <Type here>

[X] The study team plans to retain the identifiable information and/or biospecimens. Describe protocol specific plan and provide rationale: If the patient does not want to participate in the study, but still wants to be treated with laser therapy, then we would offer them treatment without enrolling them in the study. This would involve collecting their information and performing necessary examinations in order to discern the optimal treatment, but their information, response to treatment, treatment methods, or any data pertaining to the patient would not be included in the study. The patient would simply be enrolled in our EHR as a patient and not a subject in this study.

4. Eligibility Criteria

Identify the criteria for inclusion and exclusion.
Those who satisfy inclusion/exclusion criteria and screening procedures will be enrolled in this pilot study. Subject enrollment will include all ethnic groups and both sexes. Every effort will be made to enroll appropriate gender and minority/ethnic background representation that reflects the general population distribution seen at the University of California, Irvine, Dermatology Department Clinics. Inclusion Criteria Subjects must meet the following criteria: - Ability to understand and carry out subject instructions or be represented by a legally authorized guardian or representative - All ages. Patients younger than 4 may have difficulty cooperating with the OCT measurements because each measurement requires the patient to remain still for approximately 30 seconds. - Seeks and is scheduled for laser treatment of a skin lesion Exclusion Criteria Any of the following will exclude participation in the study: - Inability to understand and/or carry out instructions
If eligibility is based on age, gender, pregnancy/childbearing potential, social/ethnic group, or language spoken (e.g., English Speakers only), provide a scientific rationale.
[X] Not applicable: Subject eligibility is not based on these factors.

SECTION 4: RECRUITMENT METHODS

Check any of the following methods that will be used to recruit subjects for this study:
[ ] This study involves no direct contact with subjects (i.e., use of existing records, charts, specimens). Specify database or IRB-approved protocol number (HS#), if applicable: <Type here>
[X] Advertisements, flyers, brochures, email, Facebook, and/or other media. Specify where recruitment materials will be posted: Recruitment emails may be sent out to the UC Irvine Campus through approved channels such as the SOM Dean's Office. We will also contact foundations with interest in this topic including The Sturge Weber Foundation and National Rosacea Society and will have then send email advertisements to their members and newsletter subscribers. If subjects will be recruited by mail, e-mail, or phone, specify how their contact information will be obtained: Any subject recruited by email would be contacted through a general email list from those described above.    *Submit recruitment materials for IRB approval.*

[X] The study will be listed on Clinicaltrials.gov. *All clinical research must be registered.*

[X] The study will be listed on the UC Irvine Health Clinical Trials web page.

Submit the UCIMC Standard Research Recruitment Advertisement for IRB approval.

[ ] The UCI Social Sciences Human Subjects Lab/Sona Systems will be used.

Submit the Social Science Human Subject Pool Recruitment Advertisement for IRB approval.

[ ] Referral from colleagues

1. Study team will provide colleagues with UCI IRB-approved recruitment materials for distribution to potential subjects (e.g., recruitment flyer, introductory letter);
1. An IRB-approved recruitment letter will be sent by the treating physician. The letter will be signed by the treating physician and sent to his/her patients to inform them about how to contact study team members; and/or
2. Colleagues obtain permission from interested patient to release contact information to researchers.
3. Study team does not have access to patient names and addresses for mailing.
4. If colleagues will screen their patients' medical records to determine subject eligibility and approach patients directly about study participation: *Complete Appendix T to request a partial waiver of HIPAA Authorization.*

Submit recruitment materials for IRB approval.

[X] Study team will contact potential subjects who *have given prior permission to be contacted* for research studies.
Specify when and how these individuals granted permission for future contact: Study team members will also contact potential subjects by phone that have provided permission to be contacted for participation in future research studies
Many subjects contact the Beckman Laser Institute or other UC Irvine clinics who are interested in studies. There is no specific data base.

[X] Study team members will approach their own patients, students, employees for participation in the study.

[ ] Study team will screen UCIMC medical records to which they have access to determine subject eligibility. The patients' physicians will approach patients directly about study participation.

Complete Appendix T to request a partial waiver of HIPAA Authorization.

[X] Other Recruitment Methods: Study team members will also contact potential subjects by phone that have provided permission to be contacted for participation in future research studies. These patients have contacted us through our website registry, www.uciderm.com, and have consented online for us to contact them for future studies. Study team members will approach their own patients, students, employees for participation in the study. Potential subjects that are contacted by phone will be attempted to be reached a maximum of 3 times over the period of 3 months.

Recruitment Script

We are conducting a study that will help us gain more information about skin lesions, like your own, using a special imaging device and enhance the treatment of such skin lesions. We are asking other patients with similar skin lesions to participate in the study. We notice from your condition that you may qualify for this study.

The purpose of this study is to optimize the laser treatment of certain skin conditions with the help of optical coherence tomography (OCT). The device takes a simple picture of your skin that will help us with treating the lesion. These imaging methods may help us treat the lesion more effectively and document how to treat similar lesions with similar imaging characteristics on other patients in the future.

There are no risks to the imaging method as it uses infrared light, is painless, and works similarly to an ultrasound. Each scan with OCT will take about 30 seconds and more than one scan may be needed for larger lesions. Laser treatment has its inherent risks and would be the standard of care if you choose not to participate in this study.

Your participation in this study is completely voluntary, and if at any time you want to withdraw from the study, you may do so. If you are interested in participating in this study, I can give you a consent form which has more information. Feel free to take as much time as you need to decide if you want to participate and sign the form.

SECTION 5: INFORMED CONSENT PROCESS

1. Methods of Informed Consent

Indicate all applicable informed consent methods for this study. *Submit the consent/assent document(s) with your e-IRB Application (e.g., Study Information Sheet, Recruitment script, Consent Form, etc.). Only IRB approved consent forms (containing the IRB approval footer) may be used to consent human subjects at UCI.*

[X] Written (signed) informed consent will be obtained from subjects. Signed informed consent, parental permission, and/or child assent will be obtained from subjects, as applicable.

[ ] Requesting a waiver of written (signed) informed consent. Signed consent will not be obtained; consent will be obtained verbally or via the web. Informed consent, parental permission and/or child assent will be obtained from subjects, as applicable.

STOP *Complete Appendix P.*

[ ] Requesting to seek surrogate consent from a legally authorized individual. Surrogate consent may be considered only in research studies relating to the cognitive impairment, lack of capacity or serious or life-threatening disease and conditions of the research subjects.

STOP *Complete Appendix E.*

[X] Requesting a waiver of informed consent. (i.e., consent will not be obtained). *Skip to Section 5.B.*

STOP *Complete Appendix O.*

Indicate where the consent process will take place.

[X] In a private room
[ ] In a waiting room
[ ] In an open unit
[ ] In a group setting
[ ] The internet
[ ] In public setting
[ ] Over the phone
[X] Other (specify): At the initial screening, each prospective subject will be given a full explanation of the nature and purpose of the study by qualified staff. The potential subjects are scheduled for 1.5-hour appointments, but they may choose to take the consent home for further review and return to our facility at another appointment time.

3. Specify how the research team will assure that subjects have sufficient time to consider whether to participate in the research.

[X] Subjects will be allowed to take home the unsigned consent form for review prior to signing it.
[ ] Subjects will be allowed <Type here> hours to consider whether to consent.
[ ] Other (specify): <Type here>

If children are enrolled in this study, describe the parental permission process and the child assent process.

[ ] Not applicable: Children are not enrolled in this study.
Once the subjects have been identified as appropriate candidates for this pilot study, the protocol will be explained in detail to the patient and/or if appropriate the parent or legal guardian at a convenient time for the patient/parents by the physician investigators. Subjects will be considered appropriate if they have a skin area of interest for imaging and laser treatment is planned. Consent form, and HIPAA authorization form will be obtained including written UCI assent forms, from eligible infants/children/minor patient consent will be obtained from the patient's parent(s) or legal guardian(s).
Subjects will be informed that their participation in the pilot study is completely voluntary, and that a decision either to participate or not will not affect their care in any way. They will be given as much time as they wish to decide on participation, and will be told that they may discontinue participation at any time. Written consent will be obtained from all populations. Consent Form for Adults and assent for Children ages 13-17, and minor assent forms (ages 4-12 years old) will be obtained. Informed consent form in the way of parental permission will be collected for minors aged 0-3 who cannot yet provide assent. Parent will only be approached about participation in study after birth of their child and not before. This can be feasibly carried out via postnatal permission without compromising study design.

1. Some subjects may be vulnerable to coercion or undue influence, such as those who are economically or educationally disadvantaged, mentally disabled, or students (undergraduate, graduate, and medical students) and employees of UCI (administrative, clerical, nursing, lab technicians, post-doctoral fellows and house staff, etc.), describe the procedures to ensure the voluntary participation of these individuals.

[ ] Not applicable: Subjects are not vulnerable to coercion or undue influence.
[X] Other (specify): Please see above explanation regarding children and consent/assent.

2. Health Insurance Portability and Accountability Act (HIPAA) Authorization

Indicate all applicable HIPAA authorization methods for this study.

[ ] Not applicable: Study does not involve the creation, use, or disclosure of Protected or Personal Health Information (PHI).

[X] Requesting a Total waiver of HIPAA Authorization. HIPAA authorization will not be obtained at all for the study.

Complete Appendix T.

[ ] Requesting a Partial waiver of HIPAA Authorization. HIPAA authorization will not be obtained for screening/recruitment purposes. However, written (signed) HIPAA research authorization is obtained for further access to personal health information.

Complete Appendix T.

[X] Written (signed) HIPAA Research Authorization will be obtained from subjects. Signed authorization, parental authorization, and/or child assent will be obtained from subjects, as applicable.

Complete the HIPAA Research Authorization form.

3. Methods of Informed Consent for non-English Speakers

1. Indicate the applicable informed consent method for non-English speakers.

[ ] Not applicable: Only individuals who can read and speak English are eligible for this study. *Scientific justification must be provided in Section 3.C.2.*

[X] The English version of the consent form will be translated into appropriate languages for non-English speaking subjects once IRB approval is granted. *The translated consent form must be submitted to the IRB for review prior to use with human subjects. Only IRB approved consent forms (containing the IRB approval stamp) may be used to consent human subjects at UCI.*

[ ] Requesting a short form consent process.

Complete Appendix Q.

The short form process will be used for the following occasional and unexpected languages:

[ ] All non-English languages

[ ] All non-English languages except Spanish

[ ] Other languages (specify): <Type here>

Explain how non-English speaking subjects will be consented in their language and who will be responsible for interpreting and facilitating the informed consent discussion for the non-English speaking subjects.

[ ] At least one member of the study team is fluent in the language that will be used for communication, and that study team member(s) will be available during emergencies.


For all members of the study team responsible for obtaining informed consent from non-English speaking subjects, provide their qualifications to serve in this capacity (i.e. language fluency) in Section 2.

[X] The study team has 24-hour access to a translation service with sufficient medical expertise to discuss the research in this study.

[ ] Other (explain): <Type here>

SECTION 6: RESEARCH METHODOLOGY/STUDY PROCEDURES

1. Study Location

Specify where the research procedures will take place (e.g. UCI Douglas Hospital – Cardiac Care Unit, UCI Main Campus Hewitt Hall, UCI Health – Pavilion II, UCI Family Health Center, Anaheim, Irvine High School).


If research activities will also be conducted at non-UCI locations (e.g., educational institutions, businesses, organizations, etc.), Complete Appendix A. Letters of Permission or other documentation may be required (e.g. Off-site Research Agreements or IRB Authorization Agreements).

Subjects will be recruited from patients seen in the Department of Dermatology clinics at the University of California Irvine (UCI). After explaining the nature, rationale, objectives, benefits, and risks of the pilot study to the patients, they will be asked to consent to the study. Patients who agree to participate will sign an informed consent form before their enrollment into the study.

2. Study Design

Include an explanation of the study design (e.g., randomized placebo-controlled, cross-over, cross-sectional, longitudinal, etc.) and, if appropriate, describe stratification/ randomization/blinding scheme.

This is a longitudinal study with matched prospective controls. The patients will undergo treatment and follow-up over the course of 1-7 months. Their results will be compared to that of matched prospective controls with similar treatment and follow duration. There is no placebo, and patients will not be blinded.
Patients will be stratified based on their lesion type and the size of the lesion as these factors may impact the response to laser treatment and thus the data measurements from OCT. Photographs of the patients' treated lesions will be rated for lesion improvement by blinded physicians. OCT measurements of the lesion of interest will be used to validate the improvement and cosmetic results.

Provide precise definitions of the study endpoints and criteria for evaluation; if the primary outcomes are derived from several measurements (i.e., composite variables) or if endpoints are based composite variables, then describe precisely how the composite variables are derived.

Primary endpoints include photographic improvement of the lesion(s) of interest after 1 or more laser treatments. Two board certified dermatologists grade the degree of improvement (clearance of the lesion) in quartiles (no clearance=0-25, mild clearance=26-50, good clearance=51-75, excellent clearance=76-95, complete clearance=96-100). It will be up to the experienced treating dermatologist to determine the number of treatments necessary for maximum clearance of the lesion(s).
Secondary endpoints include measurements with OCT, which show reduced lesion thickness, lesion size, size of blood vessels, and density of blood vessels, and number of superficial blood vessels.

3. Research Procedures

Provide a detailed chronological description of all research procedures.

A screening log of all potential subjects will be kept at our site. All screening evaluations must be reviewed by the investigator to establish patient eligibility prior to registering the patient for this study.
The following screening evaluation should be completed for all subjects on the first visit:

- Informed consent and photograph release form
- Focused medical history including diagnosis of lesion if applicable. This includes general questioning about the patient's health, well-being, allergies, and medications, and history of the skin lesion in question as identified by the patient and confirmed by the physician.
- Focused skin exam. This includes a detailed medical examination of the skin lesion in question.
- Documentation of area of skin to be studied. This will be determined by the patient's indication and confirmed by the physician.

On visit number one of the study, patients will consent to the study, and an area of skin to be studied will be photographed by digital photography. If the study area is on the face, subjects will be offered to protect their identity.
Non-invasive imaging will then be performed with OCT. Each individual scan with OCT takes about 30 seconds to complete, and we may perform multiple scans on larger lesions. Based on the data and information obtained, the appropriate laser device and settings will be applied for the most optimal treatment to achieve the best results with the fewest side effects. Then laser treatment will be performed on the lesion of interest. Immediate post-treatment imaging and photography will be conducted to assess the results of the treatment. This first visit should take no more than 1.5 hours: approximately 20 minutes for a medical history and focused skin examination, 30 minutes for imaging including photographs, and 30 minutes for laser treatment. These times are all maximums and will likely be shorter. The patient may take as long as needed to consent and is permitted to take the consent form home and return another day to sign and enroll.
Some subjects may be asked to participate in more than one imaging session. They will have the option of refusing participation in additional sessions. Follow-up examinations will be performed every 4 weeks. During these examinations, photography and imaging of the lesion of interest will be performed with optional laser treatments to be performed at the discretion of the treating physician and the patient. If no laser treatment is necessary, then the visit should take no more than 30 minutes for a quick follow-up and imaging. Additional laser treatment will require no more than 30 minutes to complete. The number of follow-ups is also determined at the discretion of the treating physician and the patient but could range from 1 to 6 depending on the response of the lesion to treatment.

Matched prospective controls will be gathered to be compared against the imaged, treated, experimental group. The prospective controls will be matched to age, gender, skin type, and type of skin lesion. They will be gathered via a retrospective chart review by abstracting and data directly from our own records.
Describe the duration of a subject's participation in the study. If there are sub-studies, include duration of participation in each sub-study.
For each visit: history and skin examination-30 minutes, imaging – up to 30 mins, and laser treatment – up to 30 mins. These are all maximums and will likely be shorter. At a follow-up, the patient may or may not receive a laser treatment thus shortening the visit. A patient would be expected to have 1-6 follow ups depending on their response to treatment, so their maximum time in this study could range from about 1 to 6 months. Each follow-up visit is made about 4 weeks from the prior visit.
List data collection instruments (e.g., measures, questionnaires, interview questions, observational tool, etc.).  *Investigator-authored, non-standardized, or un-validated measures must be submitted for review.*
Standardized photography, OCT

4. UCIMC Supplementary Clinical Services

If a UCIMC clinical unit/department (e.g., phlebotomy for blood draws, pharmacy for dispensing study drug(s), radiation services for X-rays, MRIs, CT scans, and Neurology for lumbar punctures) will perform research-related procedures: 1. List the research procedure (e.g. lumbar puncture, MRI, CT Scan), and 2. Identify the unit/department that will perform the procedure.
[X] Not applicable: This study does not involve the services of a UCIMC clinical unit/department.

3. Privacy

Privacy is about the subject's ability to control how much others see, touch, or collect information about the subject. Indicate <u>all</u> of the following methods that will be used to assure subject privacy. *Violations of privacy include accessing a subject's private information without consent, asking personal sensitive information in a public setting, being audio recorded or photographed without consent.*

[X] Research procedures (including recruitment) are conducted in a private room.
[X] Use of drapes or other barriers for subjects who are required to disrobe.
[X] Only sensitive information directly related to the research is collected about subjects.
[ ] When information is collected from internet sources, the internet site's privacy statement will be reviewed and followed.

Provide a copy of the Data Use Policy to the IRB.

[ ] Other (specify): <Type here>

4. Use of Existing Biological Specimens and/or Existing Information/Data

For studies that involve use of existing (i.e. on the shelf; currently available) specimens:

1. Indicate the source of the specimens and whether the specimens were originally collected for research purposes.
2. Explain how the existing specimens will be obtained.

[X] Not applicable: This study does not involve use of existing biological specimens.

Source: Indicate <u>all</u> that apply:

[ ] UCI/UCIMC
Originally collected for research purposes: **[ ]** YES; UCI IRB number (i.e. HS#): <Type here>
[ ] NO; explain: <Type here>

[ ] UCIMC Pathology Biorepository will provide specimens.

[ ] Non-UCI Entity; specify: <Type here>
Originally collected for research purposes: **[ ]** YES

Submit a copy of the IRB Approval Notice and Consent Form for the original collection.
[ ] NO; explain: <Type here>

[ ] Other; explain: <Type here>

For studies that involve use of existing (i.e. on the shelf; currently available) clinical data:

1. Specify the source of the clinical data.
2. Explain how the study team will access the clinical data. *Access to UCI Medical Center medical records for research purposes outside the capacity of the Honest Broker Services, such as access to physician notes, must be obtained from the Health Information Management Services*.

For investigator initiated/authored studies <u>only</u>, submit a data abstraction sheet that includes a complete list of data elements/information that will be collected from (existing) records or submit the case report form (CRF; eCRF).

[ ] Not applicable: This study does not involve use of existing clinical data. *Skip to Section 6.G.*

Source: Indicate <u>all</u> that apply:

[X] UCI/UCIMC.

[ ] non-UCI Entity; specify: <Type here>

How Obtained: Indicate <u>all</u> that apply:

[ ] The study team will request specific patient information/data from UCIMC Health Information Management Services.

[X] The study team will review their patients' records and abstract data directly from those records.

[ ] The study team will request specific patient information/data from UCI Health Honest Broker Services. Describe the following:
Cohort selection criteria (e.g., use the available Clinical Terms from the Cohort Discovery Tool such as Demographics: Gender, Diagnoses: Asthma, Procedures: Operations on digestive system): <Type here>

Expected cohort size/patient count: <Type here>

Cohort attributes or data elements (e.g., lab test values, medication, etc.): <Type here>

[ ] Other; explain: <Type here>

For studies that involve use of existing (i.e. on the shelf; currently available) clinical data, specify the time frame of the clinical data to be accessed (e.g. records from January 2002 to initial IRB approval).

4. Collection of Photographs, or Audio/Video Recording

Describe all procedures involving the use and/or collection of photographs, or audio/video recording.

[ ] Not applicable: This study does not involve photographs or audio/video recording. *Skip to Section 6.H.*

Once the essential information has been provided to the subject and the investigator is assured that an individual candidate understands the implications of participating in this study, the subject will be asked to give consent to participate in the study by signing an informed consent form.

Specify if photographs or audio/video recording will include subject identifiable information (e.g., name, facial image). If so, indicate which identifiers will be collected.

Subject will be asked to give consent to participate in the study by signing an informed consent form and photography release form. Patient identifying information such as name and, if needed, facial image will be collected only for the purposes of their patient records, however, when evaluating photographs for the study, their name will not be released or utilized, and their identifying facial information (eyes) will be hidden. Most photographs will not be subject identifiable.

Explain whether the photographs or audio/video recording will be included in subsequent presentations and/or publications and, if so, whether subject identifiers will be included.

Publications and/or presentations that result from this study will not include subject identifiable information.

4. Sharing Results with Subjects

Describe whether individual results (results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subject or others (e.g., the subject's primary care physician). *Only tests ordered by a physician and conducted in a CLIA certified lab may be shared.* Explain what information will be shared and how the results will be shared.
[ ] Not applicable: Individual results will not be shared with subjects. Subjects are permitted to see their own photographs.
Describe whether overall study results will be shared with subjects. Explain how results will be shared.
[ ] Not applicable: Final study results will not be shared with subjects. Subjects are permitted to see their own results.

5. **Statistical Considerations** *(This section is required for Investigator-Authored Research)*

1. Statistical Analysis Plan: Describe the statistical method(s) for the stated specific aims and hypotheses. *Your analysis plans should match the stated study specific aims and hypotheses in Section 1.*
Statistical Analysis Plan Primary Objective: The outcome of degree of improvement will be compared between those previous patients that were treated conventionally as a prospective control and those prospective patients who will be treated with assistance from the OCT device. We will use a two-sample t-test to examine the difference in degree of improvement between the two groups at each treatment. Secondary Objective: We will present the mean/standard deviation and 95% confidence interval of all secondary outcomes (including lesion thickness, size, size of blood vessels, and density of blood vessels, and number of superficial blood vessels.) at each treatment.
2. Describe the primary statistical method(s) that will be used to analyze the primary outcome(s) or endpoints.
N/A
3. Describe the secondary statistical method(s) that will be used to analyze the secondary outcome(s) or endpoints.
N/A

4. If appropriate describe secondary or post hoc analyses of primary outcome(s) or other exploratory analysis.

N/A

5. Sample Size Determination**:** Explain how the overall target sample size was determined (e.g., power analysis; precision estimation), providing justification of the effect size for the primary outcome based on preliminary data, current knowledge/literature and/or cost consideration; if appropriate, provide sample size justification for secondary outcomes. Power analysis should (at least) match the primary outcome/endpoint.

Literature indicated that laser treatment of skin lesions yields varying degree of clearance across different types of lesions. For example, the Ashinoff et al. 1991 study showed 50% lesion clearance after 3 laser treatments for port wine birthmarks in 12 infants. Another Ashinoff et al. 1991 study showed 70% lesion clearance after 3 laser treatments for capillary hemangiomas in 10 infants. The Clark et al. 2002 study showed 50% lesion clearance after 3 laser treatments for rosacea in 12 adults. Last but not least, the Geronemus 1991 study showed 90% lesion clearance after 1 laser treatment for spider telangiectases in 12 adults. Based on these data, we calculated a mean of 65% (± 20%) lesion clearance after 3 laser treatments for any lesion type. Adjusting for the unique characteristics of our patient population at UCI, we estimated a mean lesion clearance of 40% (± 20%) after 1 laser treatment for any lesion type.

The two studies of laser treatment with OCT imaging assistance, Weibel et al. 2016 and Weibel et al. 2018, demonstrated that the depth of lesions and the size and density of the surrounding blood vessels varied widely across patients with burn and traumatic scars and vascular hemangiomas, and that some lesions appearing to be superficial had a much deeper component than could be visualized or palpated. Based on this insight, we hypothesized that laser treatment with imaging assistance would enable dermatologists to calibrate the laser parameters precisely to the actual depth of a lesion and the actual size and density of the surrounding blood vessels; as a result, at least 60% (± 20%) of the lesion of any type would be cleared after one laser treatment with imaging assistance as compared to 40% (± 20%) without imaging assistance.

A sample size of 34 patients, including 17 patients prospectively treated with laser and imaging assistance for lesions of any type and 17 prospective controls who received laser treatment without imaging assistance, would yield 80% power to test the aforementioned hypothesis using a two-sided two-sample t test at 5% significance level.

SECTION 7: RISK ASSESSMENT AND POSSIBLE BENEFITS

A. Risk Assessment

Indicate the appropriate level of review of this study, based upon your risk assessment.

[X] This study involves greater than minimal risk to subjects and requires Full Committee review. *Skip to Section 7.B.*
[ ] This study involves no more than minimal risk and qualifies as **Expedited research**.

If this study involves no more than minimal risk, provide justification for the level of review and for all applicable Expedited Categories you have chosen.

B. Risks and Discomforts

1. Describe and assess any reasonably foreseeable risks and discomforts — physical, psychological, social, legal or other. Include an assessment of their expected frequency (e.g., common – 65%, less common – 40%, unlikely – 5%, rare - <1%) and the seriousness (mild, moderate, severe). *A bullet point list is recommended. If this study will involve the collection of identifiable private information, even temporarily, for which the disclosure of the data outside of the research could reasonably place the subjects at risk, include the risk of a potential breach of confidentiality.*

Please refer to the risk section of the consent form.

2. Discuss what steps have been taken and/or will be taken to prevent and minimize any risks/ potential discomforts to subjects. *Examples include: designing the study to make use of procedures involving less risk when appropriate; minimizing study procedures by taking advantage of clinical procedures conducted on the subjects; mitigating risks by planning special monitoring or conducting supportive inventions for the study; implement security provisions to protect confidential information.*

The study team members have extensive experience with application of imaging modalities for research. The imaging modalities described in this protocol pose minimal risk to the subjects.

C. Potential Benefits

Describe the potential benefits subjects may expect to receive from participation in this study. *Compensation is not a benefit; do not include it in this section.*

[ ] There is no direct benefit anticipated for the subjects.
There is a possibility that patients will have improved results with the laser treatment. They will possibly exhibit more clearance of their lesions, making the lesion of interest more closely and relatively resemble normal skin.

Specify the expected potential societal/scientific benefit(s) of this study.

This may improve and guide future laser treatments for different types of skin lesions.

SECTION 8: ALTERNATIVES TO PARTICIPATION

Describe the alternatives to participation in the study available to prospective subjects. Include routine (standard of care) options as well as other experimental options, as applicable.
[ ] No alternatives exist. The only alternative to study participation is not to participate in the study. **[X]** There are routine standard of care alternatives available; specify: Alternative to participation would be standard of care treatment with no guidance by skin imaging or no treatment. **[ ]** There are other alternatives to study participation; specify: <Type here>

SECTION 9: SUBJECT COSTS

Indicate below if subjects or their insurers will be charged for study procedures. Identify and describe those costs**.**
[ ] Not applicable: This study involves no interaction/intervention with research subjects. *Skip to Section 10.* **[ ]** This study involves interaction/intervention with research subjects; however there are no costs to subjects/insurers. **[X]** This study involves interaction/intervention with research subjects, and there are costs to subjects/insurers: Costs will cover the medical consultation and treatment for the subjects' skin conditions. There is no cost for imaging, but subjects or insurers will pay for the standard of care laser treatment. Patients seeking care will undergo laser treatment if it is indicated by the physician whether or not they desire to be part of the study.
If subjects or their insurers will be responsible for study-related costs, explain why it is appropriate to charge those costs to the subjects or their insurers. Provide supporting documentation as applicable (e.g., study procedures include routine (standard of care) procedures; FDA IDE/HDE/IND letter that supports billing to subjects).
[ ] Not applicable: The study involves no costs to subjects for study participation. **[X]** Study related costs will be billed to subjects or their insurers for the following reasons: The subjected will undergo professional medical consultation and treatment for their skin conditions. **Laser treatments will be standard of care.**

SECTION 10: SUBJECT COMPENSATION AND REIMBURSEMENT

If subjects will be compensated for their participation, explain the method/terms of payment (e.g., money; check; extra credit; gift certificate).

[ ] Not applicable: This study involves no interaction/intervention with research subjects. *Skip to Section 11.*
[X] No compensation will be provided to subjects.
[ ] Compensation will be provided to subjects in the form of cash/gift certificate.
[ ] Compensation will be provided to subjects in the form of a check issued to the subjects through the UCI Accounting Office. The subject's name, address, and social security number, will be released to the UCI Accounting Office for the purpose of payment and for tax reporting to the Internal Revenue Service (IRS).
[ ] Other: <Type here>

Specify the schedule and amounts of compensation (e.g., at end of study; after each session/visit) including the total amount subjects can receive for completing the study. *Compensation should be offered on a prorated basis when the research involves multiple visits.*

For compensation ≥ $600, subject names and social security numbers must be collected. This information must be reported to UCI Accounting for tax-reporting purposes.

[X] Not applicable: This study involves no compensation to subjects.
Subjects will be compensated with the following schedule and amounts: <Type here>

3. Specify whether subjects will be reimbursed for out-of pocket expenses. If so, describe any requirements for reimbursement (e.g., receipt).

[X] Not applicable: This study involves no reimbursement to subjects.
Subjects will be reimbursed; specify: <Type here>

SECTION 11: CONFIDENTIALITY OF RESEARCH BIOSPECIMENS/DATA

1. Biospecimens/Data Storage

Indicate all subject identifiers that may be included with the biospecimens or collected for the research study. *If any study-related data will be derived from a medical record, added to a medical record, created or collected as part of health care, or used to make health care decisions the HIPAA policy applies. The subject's HIPAA Research Authorization is required or a waiver of HIPAA Research Authorization must be requested by completing Appendix T.*

[ ] This study does not involve the collection of subject identifiers.
Check all the following subject identifiers will be used, created, collected, disclosed as part of the research:

[X] Names	**[ ]** Social Security Numbers	**[ ]** Device identifiers/Serial numbers
[X] Dates*	**[X]** Medical record numbers	**[ ]** Web URLs
[ ] Postal address	**[ ]** Health plan numbers	**[ ]** IP address numbers
[ ] Phone numbers	**[ ]** Account numbers	**[ ]** Biometric identifiers
[ ] Fax numbers	**[ ]** License/Certificate numbers	**[X]** Facial Photos/Images
[ ] Email address	**[ ]** Vehicle id numbers	**[ ]** Any other unique identifier

[ ] Other (Specify all): <Type here>
* *birth date, treatment/hospitalization dates*

Indicate how data will be stored and secured, including electronic data as well as hardcopy data paper records, electronic files, audio/video tapes, biospecimens, etc. *If the research data includes subject identifiable data and/or Protected Health Information, the storage devices or the electronic research files must be encrypted.*

<u>Electronic Data/Files</u> (check all that apply):
[ ] Anonymous data will be maintained; no subject identifiers
[X] Coded data; code key is kept separate from data in secure location.
[X] Data includes subject identifiable information. Provide rationale for maintaining subject identifiable info)**:** The subjects are patients in our electronic medical record system; identifiable information will be maintained in that system.
[X] Data will be stored on secure network server.
[X] Data will be stored on standalone desktop computer (not connected to network/internet)
[ ] Other (specify here): <Type here>

<u>Hardcopy Data (Records, Recordings, Photographs) and Biospecimens</u> (check all that apply):
[ ] Anonymous biospecimens/data will be maintained; no subject identifiers
[X] Coded data; code key is kept separate from biospecimens/data in secure location.
[ ] Biospecimens/Data includes subject identifiable information (Provide rationale for maintaining subject identifiable info)**:** <Type here>
[X] Data will be stored in locked file cabinet or locked room.
[ ] Biospecimens will be stored in locked lab/refrigerator/freezer.
[ ] Other (specify here): <Type here>

List the location(s) where the data and/or biological specimens will be stored**.**

Imaging data will be stored in password protected computers in the Department of Dermatology sites.

If subject identifiable data will be transported or maintained on portable devices, explain why it is necessary use these devices. *Only the "minimum data necessary" should be stored on portable devices as these devices are particularly susceptible to loss or theft. If there is a necessity to use a portable device for the initial collection of identifiable private information, the research files must be encrypted, and subject identifiers transferred to a secure system as soon as possible.*

[ ] Not applicable: Subject Identifiable research data will not be transported or maintained on portable devices.
Research data will need to be maintained on the following portable device(s) for the following reason(s): Photographs will be taken using mobile devices, but they will be securely handled using only the secure electronic medical record mobile application to capture the photo. Photos are not stored on the mobile device. If for any reason, the photos are directly on the hard drives of other, portable devices, those devices will be encrypted and password protected with such photographs also password protected. At the end of their use, they will be securely deleted from the device.

1. Data and/or Biological Specimens Access

Specify who will have access to subject identifiable data and/or biological specimens as part of this study.

[ ] Not applicable: No subject identifiers will be collected.
[X] Authorized UCI personnel such as the research team and appropriate institutional officials, the study sponsor or the sponsor's agents (if applicable), and regulatory entities such as the Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP), and the National Institutes of Health (NIH).
[ ] Other: <Type here>

2. Data and/or Biological Specimens Retention

Indicate how long subject identifiable data and/or biological specimens, including the subject code key will be retained. *If more than one of the options below is applicable (e.g., the study involves children), records must be kept for the longer period.*

[ ] Not applicable: No subject identifiable research data will be retained.
[ ] Separate code key will be destroyed or subject identifiable information will be removed from the biospecimens and/or data at the earliest convenience, consistent with the conduct of this research. Specify timeframe: Immediately
[ ] Destroyed once research data is analyzed.
[ ] Destroyed after publication/presentation.
[ ] Will be maintained; specify time frame and provide the rationale: <Type here>
[ ] Will be stored and maintained in a repository for future research purposes.

Complete Appendix M

[X] Will be retained for six years as this research involves Protected Health Information (PHI) (e.g., IRB documentation, consent/assent forms – NOT the actual PHI). *Investigators must destroy PHI at the earliest opportunity, consistent with the conduct of this study, unless there is an appropriate justification for retaining the identifiers or as required by law.*
[ ] Will be retained for seven years after all children enrolled in the study reach the age of majority [age 18 in California] as this study includes children.
[ ] Will be retained 25 years after study closure as this study involves in vitro fertilization studies or research involving pregnant women.
[ ] Will be retained for two years after an approved marketing application, as this is a FDA regulated study. If approval is not received, the research records will be kept for 2 years after the investigation is discontinued and the FDA is notified.
[ ] Other: <Type here>

3. Photographs, Audio/Video Recordings Retention

If subject identifiable audio or video recordings will be collected, specify the timeframe for the transcription and describe retention/destruction plans.
[X] Not applicable: Subject identifiable audio/video recordings will not be collected. **[ ]** Audio or video recordings transcribed; specify time frame: <Type here> **[ ]** Audio or video recordings will be maintained; specify time frame: <Type here> **[ ]** Audio or video recordings maintained indefinitely; provide the rationale: <Type here> **[ ]** Audio or video recordings destroyed; specify time frame: <Type here>
If subject identifiable photographs will be collected, describe retention/destruction plans**.**
[ ] Not applicable: Subject identifiable photographs will not be collected. **[X]** Photographs will be maintained; specify time frame: Most photographs will not be subject identifiable; if imaging is used on a facial area then steps will be made to minimize subject recognition. Photographs will be maintained for 6 years. **[ ]** Photographs maintained indefinitely; provide the rationale: <Type here> **[ ]** Photographs destroyed; specify time frame: <Type here>

1. Certificate of Confidentiality

Indicate whether a Certificate of Confidentiality (COC) has been or will be requested.
[X] Not applicable: No COC has been requested for this study. **[ ]** A COC will be or has been requested for this study. *The COC application must be submitted to the IRB staff for review after IRB approval.* **[ ]** A COC has been obtained for this study. The expiration date of this COC is: <Type here>  *Provide a copy of the COC Approval Letter.*
Explain in what situations the UCI study team will disclose identifiable private information protected by a COC.
<Type here>

UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT
Consent Form for Adults (age 18 and older) and Parental Permission for Minors (0-17) and Assent for Minors ages 7-17 years of age

Skin Imaging to Inform Laser Treatments

You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed below will be available to answer your questions.

In the instance of parental permission, "You" refers to "Your child."

RESEARCH TEAM
Lead Researcher
Kristen Kelly, M.D.
Beckman Laser Institute and Department of Dermatology
Telephone Number: 949 824 7997
24 Hour Telephone number: 949 824 0606

Co-Researcher:
Christopher Zachary, MD
Mihaela Balu PhD
Patrick Lee, MD
Linda Doan, MD

STUDY LOCATION(S):
Beckman Laser Institute Medical Clinic
1002 Health Science Road, Irvine, CA 92612
Dermatology Clinic Gottschalk, 1 Medical Plaza Drive, Irvine, CA 92697

STUDY SPONSOR
UC Irvine Department of Dermatology
118 Med Surg I
Irvine, CA 92697
P (949) 824-5515
F (949) 824-7454

SUMMARY OF KEY INFORMATION:

The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.

Participation is Voluntary
You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed above will be available to answer your questions.

Study Purpose
The purpose of this research study is to identify certain types of skin lesions, obtain information about the skin lesions using imaging, and use the information to assist with laser treatment.

Study Procedures
You will undergo a regular medical history and focused skin examination of the lesion(s) in question. After consenting to the study and treatment, the physician will image the lesion(s) and apply laser treatment that is standard of care. You will be asked to return for follow-up if given laser treatment to assess the progress of the treatment.

Expected Duration
Participation will last no longer than 1-1.5 hours per visit. Each follow-up will be performed after 4 weeks, and you could be asked to return for follow-up between 1 to 6 times depending on the progress of the treatment. Each follow-up visit should take no longer than 1 hour.

Risks of Participation
There are risks to laser treatment, but no known risks to the imaging methods that will be employed. Should there be a breach in confidentiality of your data, there is a slight risk that your private medical information could be shared with individuals who are not members of the study team.

Benefits to Participants
Taking part in this study may or may not resolve or improve your skin condition. While researchers hope laser treatment with imaging will be more effective than the standard (usual) treatment, there is no proof of this yet.

Benefits to Others or Society
This study will help researchers learn more about how skin imaging could improve laser treatment and it is hoped that this information will help in the treatment of future patients with skin lesions like your own.

Alternative Procedures or Treatments
If you decide not to participate, or if you withdraw from this study before it is completed, your other choices may include:
- Getting no treatment
- Getting standard treatment for your condition without being in the study.

WHY IS THIS RESEARCH STUDY BEING DONE?
The purpose of this research study is to identify certain types of skin lesions, obtain information (such as lesion depth, depth of the most superficial part of the lesion, and the size and density of blood vessels) with the assistance of an imaging device, and use this information to assist in selection of laser settings. A skin lesion is an abnormality in the skin. Your doctor wants to take pictures of your skin by using Optical Coherence Tomography (OCT) and may treat any skin abnormalities with laser therapy. OCT can provide pictures of the skin and blood vessels in an area of the body. The laser treatment will alter the skin and the small blood vessels in the skin in order to eventually improve the skin lesion, and OCT will provide us with information about this process.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 60 participants will take part in the research at UCI.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements
You can participate in this study if you
- are able to understand carry out study

- are seeking treatment for a skin abnormality about which our device can provide information.
- From birth and above.

Exclusion Requirements
You cannot participate in this study if
- you are not able or willing to follow study instructions.

HOW LONG WILL THE STUDY GO ON?
This study includes 1-7 visits and takes no more than 60-90 minutes per visit. Each visit will be 4 weeks apart.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?
Before you can participate in the main part of the study...

1) You will be asked if you would like to take part in the study and be given informed consent. You may take as long as you need to consent to the study.
2) You will be screened by your doctor, who will perform a medical history asking about medications and allergies and a focused skin exam of the skin lesion(s) that you are seeking treatment.
3) Your doctor will identify the skin area that will be imaged, where we will take a special device to capture a detailed picture of the skin lesion. Any area of the body may be imaged except the eyelid.
4) Your skin will then be scanned: A (plastic) probe will be placed on your skin then the operator will push the “acquire button” in the software interface (on the computer). You will feel nothing since this is an optical reading (no warmth or pressure). Each individual scan will take up to 30 seconds where you will need to remain still. Multiple scans may be required for larger lesions. Total measurement time may take up to 30 minutes.
5) After looking at your skin abnormality, the researchers will determine how to best treat your skin abnormality with laser therapy, the standard of care.
6) Laser settings will be adjusted based on the clinical judgement of the physician in concordance with the standard of care.

You may be asked if laser treatment can be performed on your first visit. If so, you may be able to return for follow up and subsequent laser treatments. Each laser treatment consists of the following:
1) You will be given protective eyewear
2) Settings will be selected by the physician
3) Laser treatment will be performed.

This process should take no longer than 30 minutes.

After you complete the main part of the study…
If laser treatment is performed at a visit, you may be asked to come back for re-imaging and additional laser treatments in the future. If no laser treatment is necessary, then the visit should take no more than 30 minutes for quick imaging and a follow-up on the progress of treatment with a focused skin examination and quick history of treatment results and side effects. If further laser treatment is desired by you and recommended by the physician, an additional 30 minutes would be allotted for the laser treatment, which includes pre- and post-treatment re-imaging, which would also take no longer than 30 minutes. The number of follow-ups is determined at the discretion of the treating physician and the patient but could range from 1 to 6 depending on the response of the lesion to treatment. Each follow-up would be about every four weeks. The treating physician has extensive experience with laser treatments and will monitor patients both during and after treatments carefully.

RETURN OF RESULTS
You will be provided any clinically relevant information that may pertain to your health and the skin lesion being treated.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?

Risks of Laser treatment

Laser treatments are the standard of care, and the risk of side effects would be faced even if not participating in the study and if not undergoing imaging. Laser treatment would be done without imaging as standard procedure instead of with the imaging.

Risks of any laser treatment include:

1) Pain
2) Redness
3) Infection
4) Skin discoloration – which may be permanent
5) Blistering
6) Scarring
7) Scabbing.

Risk of imaging

The OCT procedures pose no known additional risk to you. The maximum power of the light source is 3 mW, which is spread out and comparable to halogen-bulb household flashlights. There is no excessive radiation associated with imaging. While we strongly doubt that there are risks to pregnant women and the fetus, we are currently unaware if there are any risks to the fetus in pregnancy.

Risk of breach of confidentiality

There is a small chance of a breach of confidentiality involving research data or pictures taken of you. Material will be coded but, especially if there are images of your face, however, there is a chance of you being identified.

UNKNOWN RISKS

There may be risks to being in this study that we don't know about now. You will be informed of any changes in the way the study will be done and any additional identified risks to which you may be exposed.

UNKNOWN RISKS TO WOMEN OF CHILD BEARING POTENTIAL AND PREGNANT WOMEN

While we strongly doubt that there are risks to pregnant women and the fetus, the effects of the imaging technique on a fetus are not known. If you are or you think you might be pregnant then discuss with your doctor who will perform the laser treatment.

There are no known risks to a fetus. Imaging technologies are similar to shining a flashlight on the skin and measuring the reflected light.

It is possible that there are risks, which are currently unforeseeable.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

Laser treatment without imaging.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation

You will not be paid for your participation in this research study.

Reimbursement

You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you or your insurer for your participation in this study and the imaging that will be performed. Patients or their insurer will be charged for the standard of care laser treatments. . There may be out-of-pocket expenses such as parking and transportation fees. You and /or your health

plan/insurance will be billed for the costs of any standard medical care you receive to diagnose and/or treat any medical condition(s) outside of this study. You will also be responsible for any deductibles or co-payments that would normally be associated with these standard medical costs.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?
It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?
You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to return for a final close-out visit. If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?
Subject Identifiable Data
All identifiable information that will be collected about you will be kept with the research data for at least six years. Material will be coded but, especially if there are images of your face, there is a chance of you being identified.

Data Access
The research team, authorized UCI personnel, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare. Our sponsors, Michaelson Diagnostics and Sciton, will have access to unidentifiable data from photos of your skin lesion and scans of your lesion for their device development. Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law. Research records provided to authorized, non-UCI entities may contain photographs and you may be identifiable in these. Publications and/or presentations that result from this study may contain photographs and you may be identifiable in these.

Data Retention:
The researchers intend to keep the research data in a repository for 6 years. Other researchers will have access to the data for future research. Material will be maintained indefinitely. Health information shared with other researchers will be limited to information essential for the study.

WHO WILL HAVE ACCESS TO MY STUDY DATA?
The research team, authorized UCI personnel, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare. Michaelson Diagnostics, Sciton, will have access to unidentifiable data from photos of your skin lesion and scans of your lesion for their device development.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

Future Research Use
Researchers will use your photographs, scans, and information to conduct this study. Once the study is done using your photographs, scans, and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

ClinicalTrials.gov is a Web site that provides information about clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov/, 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.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?
Investigator Financial Conflict of Interest

No one on the study team has a disclosable financial interest related to this research project.

You are being asked to allow photographs of your skin lesion. This is for research and participation in the study is voluntary. Image of the lesion is necessary to participate in this study. These photographs can be used for such purposes and in such manner as may be deemed necessary. Photographs use may include publication in a medical journal or presentation at a medical meeting. They will also be shared with our study sponsors, Michaelson Diagnostics Ltd. And Sciton Inc. All photos that will be taken and shared will be unidentifiable.

I authorize the University of California, Irvine Medical Center, and the attending physician to release photographs of my skin lesion for the reasons described above. YES, I agree with the release of my photographs NO, I don't agree with the release of my photographs.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 160 Aldrich Hall, Irvine, CA 92697-7600.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?
You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

Subject Signature	**Date**
Printed Name of Subject	
Legally Authorized Representative/Guardian Signature	**Date**
Printed Name of Legally Authorized Representative/Guardian	**Relationship to Subject**
Signature of Person Obtaining Informed Consent *(Individual must be listed on Page 1 of this consent)*	**Date**
Printed Name of Person Obtaining Informed Consent	

A witness signature is required on this consent form only if: (Researchers: check which one applies)

☐ Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐ The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐ The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐ The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

For the witness:
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____
Witness Signature **Date**

(If no witness signature is required, this witness signature section of the consent form may be left blank).

_____
Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125, Monday – Friday, 8am – 5pm; or by e-mail at IRB@research.uci.edu or by writing to us at 160 Aldrich Hall, Irvine, CA 92697-7600.

University of California Irvine Health
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy): Skin Imaging to Inform Laser Treatments

Principal Investigator Name: Kristen Kelly, MD

Sponsor/Funding Agency (if funded): UC Irvine Department of Dermatology

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that health care providers can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by UC Irvine Health it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing your health care provider to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

☒ Entire Medical Record

☐ Ambulatory Clinic Records

☐ Progress Notes

☐ Other Test Reports

☐ Other (describe):

(Description of Other Health Information)

☒ Lab & Pathology Reports

☐ Dental Records

☐ Operative Reports

☐ Discharge Summary

☐ Consultations

☐ Emergency Department Records

☐ Financial Records

☐ Imaging Reports

☐ History & Physical Exams

☐ Psychological Tests

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

_____I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

_____I agree to the release of HIV/AIDS testing information.

_____I agree to the release of genetic testing information.

_____I agree to the release of information pertaining to mental health diagnosis or treatment.

D. Who will disclose and/or receive my Personal Health Information?

Your Personal Health Information may be shared with these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor or the sponsor's representatives, or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways:

1. To perform the research
2. Share it with researchers in the U.S. or other countries;
3. Use it to improve the design of future studies;

4. Share it with business partners of the sponsor; or
5. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

If the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

☐ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

H. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

I. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

Subject

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

_____
Subject's Name (print)—*required*

_____ _____
Subject's Signature Date

Parent or Legally Authorized Representative

If you agree to the use and release of the above named subject's Personal Health Information, please print your name and sign below.

_____ _____
Parent or Legally Authorized Representative's Name (print) Relationship to Subject

_____ _____
Parent or Legally Authorized Representative's Signature Date

Witness

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

_____
Witness' Name (print)

_____ _____
Witness' Signature Date

UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT
Consent Form for Adults (age 18 and older) and Parental Permission for Minors (0-17) and Assent for Minors ages 7-17 years of age

Skin Imaging to Inform Laser Treatments

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RESEARCH TEAM
Lead Researcher
Kristen Kelly, M.D.
Beckman Laser Institute and Department of Dermatology
Telephone Number: 949 824 7997
24 Hour Telephone number: 949 824 0606

Co-Researcher:
Christopher Zachary, MD
Mihaela Balu PhD
Patrick Lee, MD
Linda Doan, MD

STUDY LOCATION(S):
Beckman Laser Institute Medical Clinic
1002 Health Science Road, Irvine, CA 92612
Dermatology Clinic Gottschalk, 1 Medical Plaza Drive, Irvine, CA 92697

STUDY SPONSOR
UC Irvine Department of Dermatology
118 Med Surg I
Irvine, CA 92697
P (949) 824-5515
F (949) 824-7454

SUMMARY OF KEY INFORMATION:

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Study Procedures
You will undergo a regular medical history and focused skin examination of the lesion(s) in question. After consenting to the study and treatment, the physician will image the lesion(s) and apply laser treatment based on the results of the imaging. You will be asked to return for follow-up if given laser treatment to assess the progress of the treatment.

Expected Duration
Participation will last no longer than 1-1.5 hours per visit. Each follow-up will be performed after 4 weeks, and you could be asked to return for follow-up between 1 to 6 times depending on the progress of the treatment. Each follow-up visit should take no longer than 1 hour.

Risks of Participation
There are risks to laser treatment, but no known risks to the imaging methods that will be employed. Should there be a breach in confidentiality of your data, there is a slight risk that your private medical information could be shared with individuals who are not members of the study team.

Benefits to Participants
Taking part in this study may or may not resolve or improve your skin condition. While researchers hope laser treatment with imaging will be more effective than the standard (usual) treatment, there is no proof of this yet.

Benefits to Others or Society
This study will help researchers learn more about how skin imaging could improve laser treatment and it is hoped that this information will help in the treatment of future patients with skin lesions like your own.

Alternative Procedures or Treatments
If you decide not to participate, or if you withdraw from this study before it is completed, your other choices may include:
- Getting no treatment
- Getting standard treatment for your condition without being in the study.

WHY IS THIS RESEARCH STUDY BEING DONE?
The purpose of this research study is to identify certain types of skin lesions, obtain information (such as lesion depth, depth of the most superficial part of the lesion, and the size and density of blood vessels) with the assistance of an imaging device, and use this information to assist in selection of laser settings. A skin lesion is an abnormality in the skin. Your doctor wants to take pictures of your skin by using Optical Coherence Tomography (OCT) and may treat any skin abnormalities with laser therapy. OCT can provide pictures of the skin and blood vessels in an area of the body. The laser treatment will alter the skin and the small blood vessels in the skin in order to eventually improve the skin lesion, and OCT will provide us with information about this process.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 60 participants will take part in the research at UCI.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements
You can participate in this study if you
- are able to understand carry out study

- are seeking treatment for a skin abnormality about which our device can provide information.
- From birth and above.

Exclusion Requirements
You cannot participate in this study if
- you are not able or willing to follow study instructions.

HOW LONG WILL THE STUDY GO ON?
This study includes 1-7 visits and takes no more than 60-90 minutes per visit. Each visit will be 4 weeks apart.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?
Before you can participate in the main part of the study...

1) You will be asked if you would like to take part in the study and be given informed consent. You may take as long as you need to consent to the study.
2) You will be screened by your doctor, who will perform a medical history asking about medications and allergies and a focused skin exam of the skin lesion(s) that you are seeking treatment.
3) Your doctor will identify the skin area that will be imaged, where we will take a special device to capture a detailed picture of the skin lesion. Any area of the body may be imaged except the eyelid.
4) Your skin will then be scanned: A (plastic) probe will be placed on your skin then the operator will push the “acquire button” in the software interface (on the computer). You will feel nothing since this is an optical reading (no warmth or pressure). Each individual scan will take up to 30 seconds where you will need to remain still. Multiple scans may be required for larger lesions. Total measurement time may take up to 30 minutes.
5) After looking at your skin abnormality, the researchers will determine how to best treat your skin abnormality with laser therapy, the standard of care.
6) Laser settings will be adjusted based on the measurements from the results of the scan.

You may be asked if laser treatment can be performed on your first visit. If so, you may be able to return for follow up and subsequent laser treatments. Each laser treatment consists of the following:
1) You will be given protective eyewear
2) Settings will be selected by the physician
3) Laser treatment will be performed.

This process should take no longer than 30 minutes.

After you complete the main part of the study…
If laser treatment is performed at a visit, you may be asked to come back for re-imaging and additional laser treatments in the future. If no laser treatment is necessary, then the visit should take no more than 30 minutes for quick imaging and a follow-up on the progress of treatment with a focused skin examination and quick history of treatment results and side effects. If further laser treatment is desired by you and recommended by the physician, an additional 30 minutes would be allotted for the laser treatment, which includes pre- and post-treatment re-imaging, which would also take no longer than 30 minutes. The number of follow-ups is determined at the discretion of the treating physician and the patient but could range from 1 to 6 depending on the response of the lesion to treatment. Each follow-up would be about every four weeks. The treating physician has extensive experience with laser treatments and will monitor patients both during and after treatments carefully.

RETURN OF RESULTS
You will be provided any clinically relevant information that may pertain to your health and the skin lesion being treated.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?

Risks of Laser treatment

Laser treatments are the standard of care, and the risk of side effects would be faced even if not participating in the study and if not undergoing imaging. Laser treatment would be done without imaging as standard procedure instead of with the imaging.

Risks of any laser treatment include:

1) Pain
2) Redness
3) Infection
4) Skin discoloration – which may be permanent
5) Blistering
6) Scarring
7) Scabbing.

Risk of imaging

The OCT procedures pose no known additional risk to you. The maximum power of the light source is 3 mW, which is spread out and comparable to halogen-bulb household flashlights. There is no excessive radiation associated with imaging. While we strongly doubt that there are risks to pregnant women and the fetus, we are currently unaware if there are any risks to the fetus in pregnancy.

Risk of breach of confidentiality

There is a small chance of a breach of confidentiality involving research data or pictures taken of you. Material will be coded but, especially if there are images of your face, however, there is a chance of you being identified.

UNKNOWN RISKS

There may be risks to being in this study that we don't know about now. You will be informed of any changes in the way the study will be done and any additional identified risks to which you may be exposed.

UNKNOWN RISKS TO WOMEN OF CHILD BEARING POTENTIAL AND PREGNANT WOMEN

While we strongly doubt that there are risks to pregnant women and the fetus, the effects of the imaging technique on a fetus are not known. If you are or you think you might be pregnant then discuss with your doctor who will perform the laser treatment.

There are no known risks to a fetus. Imaging technologies are similar to shining a flashlight on the skin and measuring the reflected light.

It is possible that there are risks, which are currently unforeseeable.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

Laser treatment without imaging.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation

You will not be paid for your participation in this research study.

Reimbursement

You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you or your insurer for your participation in this study and the imaging that will be performed. Patients or their insurer will be charged for the standard of care laser treatments. . There may be out-of-pocket expenses such as parking and transportation fees. You and /or your health

plan/insurance will be billed for the costs of any standard medical care you receive to diagnose and/or treat any medical condition(s) outside of this study. You will also be responsible for any deductibles or co-payments that would normally be associated with these standard medical costs.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?
It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?
You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to return for a final close-out visit. If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?
Subject Identifiable Data
All identifiable information that will be collected about you will be kept with the research data for at least six years. Material will be coded but, especially if there are images of your face, there is a chance of you being identified.

Data Access
The research team, authorized UCI personnel, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare. Our sponsors, Michaelson Diagnostics and Sciton, will have access to unidentifiable data from photos of your skin lesion and scans of your lesion for their device development. Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law. Research records provided to authorized, non-UCI entities may contain photographs and you may be identifiable in these. Publications and/or presentations that result from this study may contain photographs and you may be identifiable in these.

Data Retention:
The researchers intend to keep the research data in a repository for 6 years. Other researchers will have access to the data for future research. Material will be maintained indefinitely. Health information shared with other researchers will be limited to information essential for the study.

WHO WILL HAVE ACCESS TO MY STUDY DATA?
The research team, authorized UCI personnel, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare. Michaelson Diagnostics, Sciton, will have access to unidentifiable data from photos of your skin lesion and scans of your lesion for their device development.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy

Future Research Use
Researchers will use your photographs, scans, and information to conduct this study. Once the study is done using your photographs, scans, and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

ClinicalTrials.gov is a Web site that provides information about clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov/, 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.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?
Investigator Financial Conflict of Interest

No one on the study team has a disclosable financial interest related to this research project.

You are being asked to allow photographs of your skin lesion. This is for research and participation in the study is voluntary. Image of the lesion is necessary to participate in this study. These photographs can be used for such purposes and in such manner as may be deemed necessary. Photographs use may include publication in a medical journal or presentation at a medical meeting. They will also be shared with our study sponsors, Michaelson Diagnostics Ltd. And Sciton Inc. All photos that will be taken and shared will be unidentifiable.

I authorize the University of California, Irvine Medical Center, and the attending physician to release photographs of my skin lesion for the reasons described above. YES, I agree with the release of my photographs NO, I don't agree with the release of my photographs.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 160 Aldrich Hall, Irvine, CA 92697-7600.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?
You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

_____ _____
Subject Signature **Date**

_____
Printed Name of Subject

_____ _____
Legally Authorized Representative/Guardian Signature **Date**

_____ _____
Printed Name of Legally Authorized Representative/Guardian **Relationship to Subject**

_____ _____
Signature of Person Obtaining Informed Consent **Date**
(Individual must be listed on Page 1 of this consent)

_____
Printed Name of Person Obtaining Informed Consent

A witness signature is required on this consent form only if: (Researchers: check which one applies)

☐ Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐ The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐ The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐ The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

For the witness:
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____
Witness Signature **Date**

(If no witness signature is required, this witness signature section of the consent form may be left blank).

_____
Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125, Monday – Friday, 8am – 5pm; or by e-mail at IRB@research.uci.edu or by writing to us at 160 Aldrich Hall, Irvine, CA 92697-7600.

University of California Irvine Health
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy): Skin Imaging to Inform Laser Treatments

Principal Investigator Name: Kristen Kelly, MD

Sponsor/Funding Agency (if funded): UC Irvine Department of Dermatology

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that health care providers can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by UC Irvine Health it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing your health care provider to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

☒ Entire Medical Record

☐ Ambulatory Clinic Records

☐ Progress Notes

☐ Other Test Reports

☐ Other (describe):

(Description of Other Health Information)

☒ Lab & Pathology Reports

☐ Dental Records

☐ Operative Reports

☐ Discharge Summary

☐ Consultations

☐ Emergency Department Records

☐ Financial Records

☐ Imaging Reports

☐ History & Physical Exams

☐ Psychological Tests

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

_____I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

_____I agree to the release of HIV/AIDS testing information.

_____I agree to the release of genetic testing information.

_____I agree to the release of information pertaining to mental health diagnosis or treatment.

D. Who will disclose and/or receive my Personal Health Information?

Your Personal Health Information may be shared with these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor or the sponsor's representatives, or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways:

1. To perform the research
2. Share it with researchers in the U.S. or other countries;
3. Use it to improve the design of future studies;

4. Share it with business partners of the sponsor; or
5. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

If the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

☐ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

H. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

I. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

Subject

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

_____
Subject's Name (print)—*required*

_____ _____
Subject's Signature Date

Parent or Legally Authorized Representative

If you agree to the use and release of the above named subject's Personal Health Information, please print your name and sign below.

_____ _____
Parent or Legally Authorized Representative's Name (print) Relationship to Subject

_____ _____
Parent or Legally Authorized Representative's Signature Date

Witness

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

_____
Witness' Name (print)

_____ _____
Witness' Signature Date