INFORMED CONSENT, AUTHORIZATION TO PARTICIPATE IN A CLINICAL INVESTIGATION AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

Sponsor / Study Title:	**Alma Lasers Ltd. / "The Safety and Efficacy of Trio Diode Laser Module for Hair Removal Treatment in All Skin Types"**
Protocol Number:	**ALM-Trio-20-001**
Principal Investigator: (Study Doctor)	**Michael H. Gold, M.D.**
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INTRODUCTION

Before agreeing to participate in this research study, it is important that you read this form carefully. This form, called an informed consent document, describes the purpose, procedures, possible benefits, financial payment, possible risks and discomforts of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. Please take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this consent form, date it and return it to the study doctor's office. You may refuse to participate in this study and this decision will not be held against you, nor will it change any matters between you and this office, and you will continue to receive the same medical care.

The study is being conducted for Alma Lasers Ltd. Your study doctor is being paid by Alma Lasers Ltd. to conduct this study.

Advarra Institutional Review Board (IRB) has reviewed the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

NATURE AND PURPOSE OF THE STUDY

Hair removal using laser and other energy-based devices has become a very popular cosmetic procedure. Energy of a particular wavelength of light, or range of wavelengths, is absorbed by the melanin (the pigment that causes hair and skin color) in the hair follicle (where hair growth originates). This absorption produces enough heat to damage the hair follicle while leaving the surrounding tissue intact. In recent decades the most popular wavelengths used for hair removal are 755nm, 810nm and 1064nm. Each one of these wavelengths is absorbed differently in melanin and skin. Factors such as skin and hair color, hair thickness, hair depth, and hair density, affect the selection of the wavelength. The need to combine these three wavelengths was necessary in order to provide a possible treatment that would include most combinations of skin and hair types.

The current study intended to collect data regarding the safety and efficacy of hair removal study treatment for all skin types, using the Alma Lasers' Trio Diode Laser module.

STUDY DEVICE

The Soprano Titanium system is a new model for the Alma Lasers Soprano family. The system supports hair reduction using the 1064nm, 810nm, 755nm and Trio (combining 755nm, 810nm and 1064nm) modules.

The 1064nm, 810nm, and 755nm laser modules are cleared (approved) by the United States Food and Drug Administration (FDA) for a permanent reduction in hair regrowth. However, using all three wavelengths at the same time to remove hair is not an approved use for this device, therefore its use in this study is experimental. The current study is aimed to assess the safety and efficacy of hair reduction study treatment using the Trio module.

RESEARCH SUBJECT SELECTION

Up to thirty-six (36) subjects will be enrolled in this research study, being conducted at two sites.

You are being asked to participate in this research study because you are interested in undergoing axilla (arm pit) and bikini line hair removal, and you meet all of the criteria to participate in this study. To participate in this research study, you must be willing to avoid tanning for the duration of the study, avoid the use of any other hair removal therapies such as waxing, threading, depilatory, electrolysis, and other light treatments, agree to shave the study treatment area prior to the study treatment, avoid the use of topical prescription or OTC (over the counter) meds in the study treatment area for the duration of the study, and use a medically acceptable form of birth control during the entire course of the study (if of childbearing age).

It is important that you answer all of the screening questions completely. You must disclose all past and present diseases, allergies and all medications that you are taking, including prescription and nonprescription drugs. There may be reasons why you cannot participate in this study. The study doctor or study staff will discuss these with you.

PHOTO RELEASE CONSENT

This study requires that photographs of your axilla and bikini line will be taken.

By signing and dating this form, you are allowing the sponsor (Alma Lasers Ltd.) to use the photos taken during the study for educational and publication purposes. Your name or other personal information will not be used.

STUDY DESIGN AND DURATION

Your participation in this study is up to 9 months. If you agree to participate in this study, you will be required to make up to 6 visits. The first visit will be a screening visit in which the study doctor will determine if you can participate in the study. If found eligible for the study, you will undergo 4 hair removal study treatments. The first study treatment may be performed on the same day of the screening visit. A follow-up visit will be scheduled for you 3 months after the last study treatment.

STUDY PROCEDURES

Screening (Visit 1)

At the screening visit, you will be asked to sign and date this Informed Consent Form prior to any study procedures being performed. You will be asked for general information such as your age and weight. In addition, you will be asked to provide medical information (such as medical history and medications used) and cosmetic products used. A physical evaluation and vital signs assessment will be performed, you will undergo a test spot using the study device to ensure your eligibility to the study treatment, and you will be asked to perform a pregnancy urine test (for women of childbearing potential) to rule out pregnancy. The study doctor will review whether you are eligible to participate in the study according to inclusion-exclusion criteria.

Shaving instructions

- Subject must shave both sides of axilla and bikini area two weeks prior to the first treatment (Visit 2) and the 3-month follow-up visit and must avoid shaving during these two weeks.
- Subject must shave both sides of axilla and bikini area 48 hours prior to the 2nd to 4th treatment visits (Visits 3-5).

Study Treatment Visits (Visit 2-5)

Four (4) study treatment visits will be carried out with an interval of 6 weeks in between. Prior to each study treatment, you will be asked to inform the study staff about any change in medication intake/treatments since your last visit and hair removal methods used between study treatments. You will be requested to perform a pregnancy urine test (for women of childbearing potential) to rule out pregnancy and you will be asked to provide information about adverse events (side effects) you may have experienced following the last study treatment.

Immediately before the first study treatment, the study doctor will photograph the study treatment areas, for baseline assessment of hair count (you will be asked not to shave the study treatment area at least 2 weeks prior to this visit).
At each study treatment visit, the investigator will assess your axilla and bikini area for erythema (redness), edema (swelling), dryness, and peeling, before and after each study treatment and you will be requested to rate any sensation of stinging, tingling, itching, and burning at the axilla and bikini area on a scale of 0-4 (when "0" indicate none and "4" indicate sever). In addition, at the end of each study treatment, you will be requested to rate study treatment-related pain on a scale of 0-10, for each treated area (axilla and bikini line, right and left).

Follow-up Visit (Visit 6)
Follow up visit will take place 3 months after the last study treatment. During this visit, you will be asked to inform about any change in medication intake/treatments since last visit. You will be requested to provide information about adverse events (side effects) you may have experienced following the last study treatment.
The study doctor will photograph the study treatment areas, for the assessment of hair count (you will be asked not to shave the study treatment area at least 2 weeks prior to this visit) and you will be requested to fill in a subject satisfaction questionnaire, for each treated area (axilla and bikini line, right and left).

Withdrawal Procedures
If you withdraw early from the study, for any reason, you will be asked to complete the discharge procedures as outlined in the Follow-up Visit section listed above.

RESTRICTIONS/RESEARCH SUBJECT RESPONSIBILITIES
As a research subject you will be asked to complete the study procedures for this study, come to the study clinic for all of your scheduled visits, follow the instructions listed in this informed consent form, and notify the study doctor if any information regarding your health or availability to participate in this study changes.

RISKS AND DISCOMFORTS
The procedures used in this study may cause all, some, or none of the listed risks/side effects. In addition, there is always the possibility of previously unknown or uncommon side effects.

The possible risks of hair removal study treatment procedure using the study device may include:

- Pain or discomfort
- Erythema (redness) or edema (swelling)
- Irritation, itching or mild burning sensation
- Blisters
- Hypopigmentation or hyperpigmentation (patches of skin that are lighter or darker than your overall skin tone)

- Paradoxical (inconsistent or abnormal) hair growth (increase rather than the expected decrease in hair growth)
- Fragile skin (rare)
- Bruising (rare)
- Infection (rare)
- Persistent urticaria (Hives - itchy swollen areas on the skin) (rare)
- Scaring (rare)
- Burns (rare)
- Eye damage (rare) – may be severe.
- Hyperhidrosis (excessive sweating) (rare)
- Mild crusting (rare) and bleeding (rare)

UNKNOWN/UNFORESEEABLE RISKS
In addition to the risks listed above, there may be some unknown or infrequent and unforeseeable risks associated with the use of this study device. You will be informed in a timely manner both verbally and in writing of any new information, findings or changes to the way the research will be performed that might influence your willingness to continue your participation in this study.

RISKS TO THE UNBORN
***Pregnancy/Fetal Risks*:** The effects of hair removal study treatment procedure, using the study device, on an unborn child are unknown **and may be hazardous**.

If you think that you have become pregnant before the study treatment or during the study, it is important that you inform the study doctor immediately. If you become pregnant or think that you may be pregnant, you will be removed from the study and the study doctor will refer you to seek obstetric care, the cost of which will be your responsibility.

BENEFITS
After the study treatment procedure, you may experience a reduction in hair density in the treated areas. Response to this study treatment is different for each individual, and we cannot and do not guarantee or promise that you will receive any benefits from this study.

COSTS
Office visits, examinations, and study procedures will be provided at no cost to you. There will be no costs to you other than for travel for your participation in this study.

PAYMENT
You will be paid $50 per each visit you complete, excluding screening visit, to a maximum of $250. If you are unable to complete the study, if you voluntarily leave the study, or if the study is stopped early, you will be paid a pro-rated amount for the visits completed. You will be paid upon your completion of participation, within 30 days of your last visit.

ALTERNATIVES

Alternative treatments for hair removal include:

- Traditional treatments such as shaving, plucking, waxing, threading, and chemical depilatories. These methods only produce short-term results
- Longer-lasting methods include electrolysis, intense pulsed light (IPL) and alternative devices for lasers hair removal treatments, aiming to provide the same benefits as the study device

The study doctor will discuss the benefits and risks of other treatments with you. While participating in this study, you should not take part in any other research project without approval from your study doctor.

RIGHT TO WITHDRAW OR REMOVAL FROM STUDY

Your study participation is voluntary. You are free to withdraw from this study at any time, and you agree to inform the study doctor immediately if you intend to withdraw for any reason. To terminate your participation in this study, you must contact the study doctor at the contact information listed on page one of this informed consent form. You may be asked to come to the study clinic or study doctor's office to complete some end of study procedures. Your decision to participate in this study or to withdraw from this study will not influence the availability of your future medical care and will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw from this study at any time.

You agree that the study doctor in charge of the study can remove you from this study without your consent for any reason, including, but not limited to:

- His/her judgment that any condition or circumstance may jeopardize your welfare such as increased risk, change in potential benefit, or the integrity of the study
- Your failure to follow the instructions of the study doctor(s)
- If the study is stopped by the sponsor and/or study doctors participating in the study prior to completion

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00046147.

CONFIDENTIALITY AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

This study can be performed only by collecting and using your protected health information. Your study records will be kept as confidential as possible under local, state and federal laws. Personnel from the following organizations may examine your study records, including information that may identify you by name:

- The sponsor, Alma Lasers Ltd.
- Personnel associated with this study (including monitors and auditors)
- The Institutional Review Board (IRB)
- Regulatory agencies, such as the United States Food and Drug Administration (FDA)

Because of the number of individuals who may see your records, absolute confidentiality cannot be guaranteed.

Protected health information that may be used and disclosed includes that which is obtained to determine your eligibility to participate and that which is collected from the procedures that are carried out. It may identify you by name, address, telephone number, Social Security Number, study number, date of birth or other identifiers. Once the information is disclosed, it is possible that it may be re-disclosed, at which time it may no longer be protected by federal regulations but may be by state laws. If the final study data are prepared for publication and other reports, your identity will not be revealed. Under these federal privacy regulations, you have the right to see and copy any of the information gathered about you, until your study records are no longer kept by the study doctor. However, it may not be available until the study has been completed.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of Alma Lasers Ltd.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other U.S. federal and state agencies.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To evaluate the efficacy and safety of the study treatment.
- For other research activities related to the study treatment.

You may, by written notice to the study doctor at the address listed on the first page of this form, cancel your authorization to use or disclose your personal information at any time. If you withdraw your authorization, the information collected up to that time may still be used to preserve the scientific integrity of the study. By signing and dating this form, you authorize these uses and disclosures of your personal information. If you do not authorize these uses and disclosures, you will not be able to participate in the study. This authorization does not have an expiration date. In California and any other state that requires an expiration date, this authorization will expire 50 years after you sign and date this authorization document.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____	_____
Research Subject's Name (printed)	Research Subject's Date of Birth
_____	_____
Research Subject's Signature	Date

IN CASE OF INJURY

If a research-related injury occurs, the Sponsor, Alma Lasers Ltd. will pay for any treatment of research-related injury to the extent that such costs are not covered by your health insurance policy. However, the Sponsor will not pay for pre-existing conditions or for any conditions unrelated to the study treatment. You must follow the instructions of the study doctor to be eligible for this coverage. Also, the Sponsor has no plans to compensate you for wages associated for lost time at your workplace or dissatisfaction with study treatment outcome.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing and dating this consent document.

If you are injured during this study, your study doctor will discuss with you the available medical treatment options.

By signing and dating this form, you **have not** given up any of your legal rights.

POSTING OF RESEARCH STUDY ON WEB

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.

CONSENT STATEMENT

I have read in a language I understand well the above description of this research study. I have been informed of the risks and benefits, and all my questions have been answered to my satisfaction. By signing and dating this form, I voluntarily consent to participate in the research study and authorize the release of my personal health information.

I authorize the use and disclosure of my personal health information for the purposes of this study. Refusal to give my authorization means I cannot participate, but my future medical care will not be affected.

I voluntarily agree to participate in this study. I will be given a copy of this signed and dated form.

_____ _____

Research Subject's Name (printed) Research Subject's Date of Birth

_____ _____

Research Subject's Signature Date

_____

Study Doctor's/Study Staff's Name (printed)

_____ _____

Study Doctor's/Study Staff's Signature Date

Copy of signed and dated consent form given to the research subject on (date) _____ by (initials) _____