Informed Consent Form

Participant Name: _____ Participant Number: _____

STUDY TITLE: Intralesional Injections of Triamcinolone for Acne Vulgaris

STUDY NUMBER: ATM-2201

INVESTIGATOR:	**CONTACT PHONE:**	**SPONSOR**
Dr. Sunil Dhawan	510-797-4111	ACOM Labs, Inc.

INTRODUCTION

You are being invited to participate in a research study. This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take as long as you need to read this form carefully and to understand any accompanying information. After reading this information sheet, take time to think about this research study and discuss it with anyone you want to. You are entirely free to decide to accept or refuse to participate in this study. If you decide to participate, please sign and date this informed consent form. You will be given a copy of this information and consent form once signed.

PURPOSE OF THE STUDY

The purpose of this study is to investigate the safety of injections of triamcinolone into acne lesions using an Intradermal Needle Adapter. The study will also assess how acne lesions respond to these injections.

Triamcinolone is a type of corticosteroid that is commonly used to treat acne lesions by intralesional injections (i.e., injection of triamcinolone directly into the acne lesion). A total of 0.05 mL to 0.15 mL of triamcinolone 0.5% to 2.5% will be injected into at least one, and up to three of your acne inflammatory lesions.

The intradermal needle adapter is a stainless steel accessory that slips on the end of a standard needle and reduces the effective length of the needle to 1mm.

A total of 20 participants, male or females 18 years of age or older will take part in this study, which will be conducted at the study doctor's office.

The study is sponsored and financed by ACOM Labs, Inc. It has been reviewed and approved by an Independent Review Board (Veritas IRB).

PROCEDURES

Your participation will last up to 14 days, during which there will be 6 visits to the study doctor's office. After the first study visit, you will return at 24 hours, 48 hours, 72 hours, Day 7, and Day

14. At Visit 1, if you are eligible to participate in the study, you will receive study injections into up to 3 inflammatory acne lesions.

All study participants will receive study treatment. Study treatment will be provided to you at no charge.

To participate in this study, you must agree to the following:

- You must review and sign this informed consent form and a Health Insurance Portability and Accountability Act (HIPAA) release. If you live in California, you will also be asked to sign the California Experimental Research Subject's Bill of Rights. In order to participate in this study, you must also sign the photography/video release section of this informed consent form which allows photographs/video of your acne vulgaris affected areas to be used for the research purposes of this study. All your questions should be answered before signing these forms. Also, if you agree, the study doctor will inform your primary physician (if you have one) about your participation in the study to ensure that you have adequate medical follow-up during and after this study.
- You must follow the study instructions and those of your study doctor. This includes returning promptly to your study doctor's office for all necessary study follow-up visits, report any changes in your medications (over the counter and prescription) and report any changes in how you feel to the study doctor.
- Current acne treatment: If you are currently using acne medication you can continue to do so. You will not be required to stop taking such treatment but will need to continue using your medication at the current dosage and frequency.
- Pregnancy: You cannot participate in this study if you are pregnant. If you are a female and are able to become pregnant, you must perform a urine pregnancy test to confirm that you are not pregnant.
- If you discontinue study participation early (for any reason), you will be invited to be contacted by the study doctor for a follow-up (telephone or clinic visits) to ensure that you are not experiencing side effects.

Visit 1 (Day 1- Baseline): This visit will last about 90 minutes and will take place at the study doctor's office.

- You will review and sign this Informed Consent form.
- The study doctor will determine if you are eligible to participate in this study.
- Your medical history, current medical conditions, and medication use will be reviewed.
- A urine pregnancy test will be performed if you are a woman of childbearing potential. If you are pregnant, you will not be enrolled into the study.
- The study doctor will assess the severity and general appearance of your acne.
- The study doctor will assess the size, severity and general appearance of the acne lesions that will be injected.
- Before the injection, you will be asked how painful are the acne lesions that will be injected, and the study doctor will take photographs of your acne lesions.
- The study doctor will then inject the triamcinolone into at least one, and up to three of your acne lesions using the study device. The study doctor will record a video of the injection procedure for at least one of the acne lesions.

- After the injection, you will be asked about how you are feeling and if you experienced any side effects, as well as the level of pain associated with each injection.
- The study doctor will take photographs of your treated acne lesions.

Visits 2, 3, 4, 5, and 6 (24hrs, 48hrs, 72hrs, Day 7 and Day 14): Each visit will last about 45 minutes and will take place at the study doctor's office.

- You will be asked if you experienced any side effects or used any new medications or treatments since the last visit.
- The study doctor will assess the size, severity and general appearance of the acne lesions that were injected.
- The study doctor will take photographs of your treated acne lesions.
- You will be asked how painful your treated acne lesions are as well as how satisfied you are with the study treatment.

STUDY EXIT: Before exiting the study, the study doctor will make sure that if you experienced any side effects, these are appropriately resolved. If all side effects have resolved, your study participation will be considered fully completed and you will exit the study. If a side effect(s) has not yet resolved, the study doctor may need to contact you or ask you to return at a later date so that he/she can collect final data on the side effect(s) and make sure that you are OK.

ADJUSTMENT OF STUDY VISITS DUE TO PUBLIC HEALTH EMERGENCY OF COVID-19

Remote study visits may be conducted if the local situation does not allow for an on-site study visit to be conducted or if you do not wish to come to the study site. However, not all study procedures may be performed remotely, and you may still need to present yourself for an in-person visit to complete certain study procedures.

Remote study visits may be conducted via video conferencing using a web-based platform. Phone calls may also be used to perform some assessments if you do not have video conferencing capabilities or if technical requirements such as internet connection cannot be met at the time of a remote study visit.

Visit 1 cannot be done remotely. An on-site visit is required as this is when the study doctor will perform injections into your acne lesion(s). If you cannot come to the site, you will not be able to participate in the study.

In case regular visits are disrupted due to the COVID-19 pandemic, before the planned visits, the study staff will contact you to see if you can come to the site. If not, the visit may be done remotely, and the study doctor will perform all the assessments that can be done remotely. If you cannot come to the site for all study visits you may still be able to continue in the study.

Before the scheduled date of a remote visit:

- The study staff will find out if you can accommodate video conferencing (e.g., internet access, PC, smartphone, video conference apps, etc.).
- The study staff conducting the remote visit will obtain your verbal consent before proceeding with the visit. The study staff will also explain to you how the visit will be conducted.
- The study staff will send to you all required study material to conduct the visit (e.g., study questionnaires, etc.).

- A test call may also be completed prior to the appointment.

On the day of the scheduled remote visit:

- Both you and the study staff will confirm your identities with one another before starting the video conference visit. For example, the study staff will state their name and role and you may identify yourself by using two identifiers (e.g., name and date of birth) and a photo ID.
- The study assessments will be adjusted accordingly in order for the study staff to conduct them remotely.

EXCLUSIONS

Since there may be unknown risks to pregnant women, their unborn children and breastfed infants, you will be excluded from the study if you are pregnant. If you are able to become pregnant you must have a urine pregnancy test before receiving study product. If you are pregnant, you will not be allowed to receive treatment with the study product.

You understand that you should not be enrolled into this study if you are pregnant. If you become pregnant during the study and you choose to continue the pregnancy, you must immediately inform the study doctor. If you agree, you will give Dr. Sunil Dhawan access to your and/or your infant's medical records for the time of pregnancy and for at least 8 weeks following delivery if you become pregnant during the study.

PARTICIPATION AND TERMINATION

Your participation in this study is voluntary. You may refuse to participate. If you choose to participate, you can change your mind at any time and withdraw from the study. Refusal to participate or withdrawal from the study will not compromise your ongoing or future medical care or benefits to which you are otherwise entitled at this office. If you do participate and your symptoms do not improve, or if you have an adverse experience, you can withdraw from the study at any time. Your doctor will then treat your condition appropriately.

If you experience any study-related illness or injury, necessary medical treatment will be available to you at no additional cost. You will not waive any of your legal rights by signing this consent form. If you experience an injury, illness or side effect, you should contact: Sunil Dhawan, M.D. 24 hours a day at: 510-797-4111.

Your participation in this study can also be terminated, without your consent, by the study doctor if it is determined to be in your best interest or if you fail to follow the study doctor's instructions. Specific reasons why you may be removed from this study without your consent include but are not limited to the following:

- A condition or circumstance exists that may jeopardize your welfare or study integrity.
- Your failure to follow the instructions of the study doctor.
- The study is stopped by the sponsor or doctor participating in the study prior to completion.

RISKS

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. If necessary, the study doctor may give you medicines to help lessen side effects. You should talk to your study doctor about any side-effects you experience while taking part in the study.

Possible risks associated with the Study Treatment: Intralesional injection of triamcinolone may produce side effects. Typical side effects reported for are usually limited to the injection site and may include pain due to injection, flushing, change in skin pigmentation, bruising, shiny-appearing skin, redness, and/or thinning of skin.

Unknown risks: The possibility of unknown risks exists. The study product may have side effects that no one yet knows of, and the fetus of a pregnant woman or the infant of a nursing woman becomes at risk as well.

Allergic reactions: The study product may have a potential risk of an allergic reaction. Allergic reactions may vary from mild (rash, hives, itching) to severe reactions such as anaphylaxis. Signs that you may be having a severe allergic reaction are difficulty breathing, wheezing when you breathe, sudden change in blood pressure (making you feel dizzy or lightheaded), swelling around the mouth, throat or eyes, fast pulse, rash or itching, and sweating. Severe allergic reactions could result in permanent disability or death. You should get medical help and contact the study doctor or staff if you have any of these or any other side effects during the study.

Breach of Confidentiality: Any records that could identify you will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available.

COVID-19 Public Health Emergency: Depending on the local situation***,*** your study participation may be affected by a COVID-19-related disruption. For example, your study visit could be delayed or canceled. Also, there is a risk that you could be exposed to the virus responsible for COVID-19 while attending your study visit at the study doctor's office. Your study doctor is taking all safety precautions to reduce the risk of spread of COVID-19 and expect you to follow public health directives as well.

New information: Your study doctor or study staff will let you know if any significant new findings or additional information becomes available during the course of this study, which may affect your willingness to continue participating in this study.

BENEFITS

As with any medical research experiment, there may be certain direct benefits derived by participating in this study. Such benefits may include improvement of the acne lesions that have been injected; however, this is not guaranteed. It is possible that you receive no benefit. The results of this study may be useful in the development of a new therapy for others with similar conditions.

ALTERNATIVE THERAPY

If you decide not to participate, or if you withdraw from this study before it is completed, a variety

of alternative therapies are available to treat your acne lesions such as cosmetic and/or over the counter (OTC) products, topical treatments for acne (e.g., retinoids, antibiotics, corticosteroids, etc.). You are encouraged to discuss alternative treatments with the study doctor if you would like. You also have the option of not receiving any treatment.

COSTS AND COMPENSATION

You are not responsible for any costs for the required study visits, examinations, procedures, and study product.

You will receive $50.00 for each visit that you attend (up to a maximum of $300.00) to help defray the costs for your participation in this study. These funds will be paid at each visit. These payments are for your time, travel expenses, and inconvenience.

If you choose to leave or are withdrawn from the study for any reason before finishing all visits, your compensation will be prorated for the visits and procedures you have completed.

INVESTIGATOR PAYMENT

ACOM Labs, Inc., the manufacturer of the study product, is funding the study and will pay the study doctor for their time spent on the study. This disclosure is made so that you can decide if this relationship will affect your willingness to participate in the study.

CONFIDENTIALITY

Any information that identifies you with respect to this research study will be kept confidential.

Information in your medical records (including your identity and contact information) relating to this study will be kept as confidential as possible under laws and regulations and will not be made publicly available. If the results of the trial are published, your identity will remain confidential. Any information about you that is sent out the clinic will be coded; this means that it will not be identified by name, but only with the coded number assigned to you for this trial.

However, by signing this consent form, you allow access to your medical records. Your medical records identifying you may be reviewed by ACOM Labs, inc. (Study Sponsor, Manufacturer of the Intradermal Needle Adapter), ethica CRO Inc. (the company managing this study), and/or representatives of Veritas IRB. These individuals may directly access your original medical records to verify that research procedures were correctly followed and the accuracy of the data. The confidential nature of your medical information will be respected. Although different measures (as described above) are taken to keep your information and medical records as private as possible, your privacy cannot be 100% guaranteed or protected because it may not be possible to entirely de-identify your photos.

Regarding the photographs/videos of your acne lesions, you may be recognizable. The photographs/videos will be used only for the purposes to which you agreed on the “Photography/Video Release” section of this form. The Sponsor will not make any link whatsoever between your name and your images when using them. If your pictures are used for external communications, and your face is visible, your eyes will be covered.

The data from this study will be used for the research related to this study. It may additionally be used to support future research studies and/or to support marketing of a product. The information collected during this study will be kept on file for a maximum of 10 years after the end of the study (even if you withdraw from the study) as any data collected up to the time of your study exit will remain in the trial database and be included in the data analysis.

All data generated by this study, including data related to your participation in the study, will be stored by ethica CRO Inc. using a secure and password protected server located in Canada. Your individual data will be identified by a unique study identification number only (i.e., no personal information). Any paper records will be stored at the office of your study doctor in a secure locked room and/ or file cabinet.

You have the right to access your study records. You can request a copy of this information from your study doctor.

By signing this document, you consent to such review, inspection and disclosure.

CONTACT

If you have any questions regarding this study, your participation in it, if a research-related injury arises, or if you want to voice concerns or complaints for any reason, you should contact Dr. Sunil Dhawan at 510-797-4111.

This study has been reviewed and approved by Veritas Independent Review Board (IRB). If you have any questions about your rights as a research participant or the study doctor's responsibilities, you may contact the Manager of the Veritas Independent Review Board 24 hours per day and 7 days per week at 1-866-384-4221. An IRB is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the participant's rights and welfare in mind. If you have any study-related comments, complaints or concerns you should first contact the study doctor. Please call the IRB if you need to speak to a person independent from the study doctor and research staff, and/or if the study doctor and research staff could not be reached.

HIPAA AUTHORIZATION

(Patient Authorization for use and disclosure of Personal Health Information in Research)

I agree to permit:

(a) Dr. Sunil Dhawan at Center for Dermatology Clinical Research Inc. ("**Researchers**"),
(b) My doctors and my other health care providers ("**Providers**")
to use and disclose (release) health information about me as described below.

1. The health information that may be used and disclosed includes:

(a) all information collected during the research described in the Informed Consent Form for the study and
(b) de-identified health information in my medical records that is relevant to the study.

2. The Providers may disclose health information in my medical records to:

(a) the Researchers;
(b) the company that manufactured the product to be studied, ACOM Labs, inc., and its agents and contractors (together "Company") for any research related to this study only, including analysis of the trial findings, and to conduct additional research using such protected de-identified health information, and
(c) representatives of government agencies, review boards, and other persons who watch over the safety, effectiveness, and conduct of research.

3. The Researchers may:

(a) use and share my de-identified health information among themselves, with the Company, and with other participating researchers and laboratories to conduct the study, and
(b) disclose my de-identified health information to representatives of government agencies, review boards, and other persons who watch over the safety, effectiveness, and conduct of research.

4. The Researchers may use and share my de-identified health information as permitted by the Informed Consent Form.

5. Once my health information has been disclosed, federal privacy laws may no longer protect it from further disclosure.

6. Please note that:

(a) You do not have to sign this Authorization, but if you do not, you will not be able to participate in the study.
(b) You may change your mind and revoke (take back) this Authorization at any time and for any reason. To revoke this Authorization, you must write to Dr. Sunil Dhawan, Center for Dermatology Clinical Research, Inc, 2557 Mowry Ave, Suite 34, Fremont, CA 94538. However, if you revoke this Authorization, you will not be allowed to continue taking part in the study. Also, even if you revoke this Authorization, your Providers, the Researchers, and the Company may continue to use and disclose the information they have already collected to protect the integrity of the research or as permitted by the Informed Consent Form.

7. This Authorization does not have an expiration (ending) date

_____

Participant's Printed Name Signature Date

_____

Person Explaining Consent Printed Name Signature Date

CONSENT

IF YOU WANT TO PARTICIPATE IN THIS STUDY, please read and sign the following pages and, if applicable, the California Experimental Research Subject's Bill of Rights.

I have read this form, and I have been able to ask questions about this study. The study doctor or study staff has talked with me about this study and they have answered all my questions. I voluntarily agree to be in this study.

By signing this form, I have not given up any of my legal rights as a research participant. The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws that require additional information to be disclosed for informed consent to be legally effective. Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

You will receive a fully signed copy of this consent form for your records, and in California, a copy of the Experimental Research Subject's Bill of Rights.

Participant:

_____

Printed Name Signature Date

Person Obtaining Consent (e.g., Study Nurse, Investigator):

I attest that the above-named participant had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in this study.

_____

Printed Name Signature Date

INVESTIGATOR STATEMENT

I certify that I or my representative have explained to the above-named participant the nature and implications of this research study. I have answered all of the participant's questions and have encouraged him or her to ask any additional questions at any time during the course of the study.

Investigator/Delegate:

_____

Printed Name Signature Date

CONTACT WITH YOUR PRIMARY PHYSICIAN

I, the undersigned, confirm that:

☐ **I HAVE A PRIMARY PHYSICIAN AND**

- ☐ Agree that the study doctor contact my primary physician to inform him/her of my participation in the study ATM-2201.
- ☐ Disagree that the study doctor contact my primary physician to inform him/her of my participation in the study ATM-2201.

☐ **I DO NOT HAVE A PRIMARY PHYSICIAN**

Participant:

_____

Printed Name Signature Date

Person Obtaining Consent (e.g., Study Nurse, Investigator):

_____

Printed Name Signature Date

PHOTOGRAPHY/VIDEO RELEASE

You confirm voluntarily consenting to the taking, copyright, and use of your pictures/videos of your acne lesions. As the acne lesions will be on your face, you may be identifiable. These photos/videos will be used only for the research purposes of the study (e.g., photographic record of improvement and/or healing of the treated acne lesions, video recording of the injection procedure). You will not be able to participate if you do not consent to your pictures/videos being taken for research purposes.

YES	NO	
☐	☐	**I CONSENT TO HAVING PHOTOGRAPHS/VIDEOS OF MY ACNE LESIONS TAKEN FOR THIS STUDY**

There are other uses for your photographs/videos (e.g., publications, promotion of the study product, etc.). Please check the "Yes" box for the categories for which you give consent and the "No" box for the categories for which you do not give consent. You do not have to give consent to either of these two categories to participate in the study.

YES	NO	
☐	☐	FOR EDUCATION, PUBLICATIONS, INFORMATIONAL PURPOSES, OR RESEARCH ASSOCIATED WITH THIS STUDY
☐	☐	FOR GENERAL ADVERTISING, PUBLICITY, AND PROMOTIONAL PURPOSES

By signing this release, you do not forfeit any of your legal rights. It is within your rights to revoke this authorization for future uses at any time.

Participant:

_____

Printed Name Signature Date

Person Obtaining Consent (e.g., Study Nurse, Investigator):

_____

Printed Name Signature Date

PREGNANCY FOLLOW-UP

Only to be completed by females of child-bearing potential

I, the undersigned, confirm that:

- ☐ I **agree** to give Dr. Sunil Dhawan access to my and/or my infant's medical records for the time of pregnancy and for at least 8 weeks following delivery if I become pregnant during the study ATM-2201
- ☐ I **disagree** to give Dr. Sunil Dhawan access to my and/or my infant's medical records for the time of pregnancy and for at least 8 weeks following delivery if I become pregnant during the study ATM-2201

Participant:

Printed Name	Signature	Date

Person Obtaining Consent (e.g., Study Nurse, Investigator):

Printed Name	Signature	Date

REMOTE STUDY VISIT CONSENT

Introduction

During the COVID-19 public health emergency, your study doctor may recommend that your study visits be conducted remotely instead of in-person to ensure your safety.

Remote Study Visits involve the use of telecommunication technologies (also called telemedicine) to conduct certain procedures of the clinical trial. Remote study visits may be conducted if the local situation does not allow for an on-site study visit to be conducted or if you do not wish to come to the study site.

Remote study visits may be conducted via video conferencing using a web-based platform. Phone calls may also be used to perform some assessments if you do not have video conferencing capabilities or if technical requirements such as internet connection cannot be met at the time of a remote study visit.

Potential Benefits:

- Less time at the clinic and lower risk of exposure to COVID-19 at the site.

Risks:

There are potential risks to using telecommunication technologies to conduct remote study visits. These risks include:

- Possible technical difficulties and termination of connection may occur before or during remote study visits and the visit may not be started or ended as intended;
- In rare cases, information transmitted may not be sufficient (e.g., poor resolution) to allow for appropriate study assessments;
- Systems that meet recommended standards to protect the privacy and security of the remote study visits will be used. However, the service providers cannot guarantee total protection against hacking or tapping into the video visit by outsiders. In very rare instances, security protocols could fail, causing a breach of privacy of personal medical information.

If the remote visit does not achieve everything that is needed, you may be asked to attend a follow up face-to-face visit, or a second remote visit.

By signing this form, I understand the following:

1. I understand and accept the risks outlined above to this consent form, associated with the use of telecommunication technologies as described above.
2. I understand that the laws that protect privacy and the confidentiality of medical information also apply to remote study visits, and that no information obtained during remote study visits which identifies me will be disclosed without my consent.
3. I understand that I have the right to withhold or withdraw my consent to remote study visits in the course of the study at any time, without affecting my right to future care.
4. I understand that not all study procedures may be performed remotely and that I may still need to present myself for an in-person visit to complete certain study procedures.

Consent to Remote Study Visits

I have read and understand the information provided above regarding remote study visits, have discussed it with my study doctor, and all of my questions have been answered to my satisfaction.

YES	NO	
☐	☐	I hereby give my informed consent for the use of remote study visits (when applicable) to perform clinical trial assessments.

Participant:

Printed Name	Signature	Date

Person Obtaining Consent (e.g., Study Nurse, Investigator):

Printed Name	Signature	Date