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INTEGREVIEW IRB
JUNE 12, 2017

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF STUDY SPONSOR:	Leon Kircik, M.D.
PROTOCOL NUMBER AND TITLE OF STUDY:	ONX-1701: "The Use of Onexton in Moderate Acne Vulgaris for Patients with Skin of Color"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR):	Leon Kircik, M.D.
DAYTIME TELEPHONE NUMBER:	502-451-9000
AFTER HOURS TELEPHONE NUMBER:	502-396-5310

INTRODUCTION

You ("you" refers to you or your child throughout this consent form) have the option of participating in this medical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

The investigator is the sponsor, and is paying for this study.

You must be honest with the investigator about your health history or you may harm yourself by participating in this study.

PURPOSE OF THE STUDY

This study drug, Onexton gel (1.2% clindamycin phosphate / 3.75% benzoyl peroxide) is a topical (on the surface of the skin) gel that has been approved by the United Stated Food and Drug Administration (FDA) for the treatment of acne vulgaris.

This study is investigational and is being done to determine how well Onexton gel can treat post-inflammatory hyperpigmentation (PIH) in patients with skin of color. PIH is a condition where areas of the skin get darker after inflammation associated with acne vulgaris.

"Investigational" means the study drug being tested is not approved by the FDA for the purpose of treating PIH.

In this document, you may see the terms "medication", "treatment", and "treatment period"; these are terms used in research studies as mentioned above, this does not mean that you will be receiving medical treatment for any condition. These terms apply to the investigational study drug and parts of the study where you will be receiving this investigational product.

If you qualify for the study, you will receive a pump bottle with a sufficient supply of Onexton gel. This is known as the "study drug". It should be applied to the face once a day by rubbing it gently into the skin until it is rubbed into your entire face. Do not give the study drug to other people and keep it out of the reach of children.

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HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

The study will last up to 20 weeks and involve up to 5 visits. About 20 healthy males and females, with skin of color, ages 12 and older, are expected to be in this study.

TO BE IN THIS STUDY

You cannot be in this study if you are in another research study or if you have been in any other research study in the last 30 days. You cannot be in this study if you are taking any drugs of abuse (illegal and/or prescription) or if you have a history of illegal substance abuse in the past 6 months.

Subject Responsibilities:

While participating in this research study, you will need to:

- Be willing and able to follow the study directions and procedures
- Tell the study staff about any side effects or problems
- Ask questions as you think of them
- Tell the investigator or the study staff if you change your mind about staying in the study.
- Be willing to stop using other acne treatments while participating in this study
- Use the study drug daily as directed

WHAT WILL HAPPEN DURING THE STUDY

At each study visit, the study doctor will ask you whether you have had changes to your health or medications.

Screening:

Before the study starts, you will be asked to sign this consent form, give your health history, provide some personal information about yourself, and tell study staff if you take any over-the-counter or prescription medicines, vitamins or herbs.

The investigator will do some tests and ask you some questions to find out if you can be in the study. These tests include:

- Some physical exam procedures
- Urine pregnancy tests for female subjects at screening
- Complete surveys or answer questions about your condition
- Skin exam and acne assessments

Study Procedures:

Visit 1 (Screening)

- Informed Consent/HIPAA (privacy form)
- Urine pregnancy test (if applicable)
- The study doctor will complete some assessments on your condition

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JUNE 12, 2017**

- You will complete assessments and answer questions about your condition
- The study doctor will determine whether you are appropriate for this study

Visit 2 (Baseline Visit)

- The study doctor will determine whether you are appropriate for this study.
- Urine pregnancy test (if applicable)
- The study doctor will complete some assessments on your condition
- You will complete assessments and answer questions about your condition
- Dispense study drug

Visits 3 and 4 (Weeks 4 and 8 ± 3 days)

- Urine pregnancy test (if applicable)
- The study doctor will complete some assessments on your condition
- You will complete assessments and answer questions about your condition
- Assess treatment compliance (whether you use the medication according to instructions)

Visit 5 (Week 16 ± 5 days)

- Urine pregnancy test if applicable
- The study doctor will complete some assessments on your condition
- You will complete assessments and answer questions about your condition
- Return study drug

POSSIBLE SIDE EFFECTS AND RISKS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

Even though this drug is has been approved by the FDA, all of its side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

You must tell the investigator or study staff about all side effects that you have. If you are not honest about your side effects, you may harm yourself by staying in this study.

Below is a list of the more common side effects of the study drug:

- burning/stinging/tingling
- itching
- dry skin
- redness
- swelling of the skin
- worsening of acne
- eye irritation
- changes in skin color
- inflammation of the colon

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- sensitivity to sunlight

There is a small but real risk of allergic reactions (potentially fatal) with any medication. Signs of an allergic reaction include:

- Swelling around the face, throat, and mouth
- Itchy or runny eyes
- Runny nose and sneezing
- Skin itching, redness, swelling, or hives

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

You or your female partner must not get pregnant while in this study. The only certain way to not get pregnant is to not have sex. If you choose to have sex, you and/or your partner must use a type of birth control listed below:

- hormonal birth control (like birth control pills)
- intrauterine device (IUD) if inserted more than 90 days before the start of the study
- condoms or a diaphragm plus spermicide if started at least 14 days before the start of the study
- vasectomized partner if vasectomy was performed more than 3 months before the start of the study

Even if you use birth control during the study, there is a chance you could become pregnant. If you are pregnant or become pregnant during the study, the study drug/device or procedure may involve unforeseeable risks to the unborn baby. A pregnancy test is not always right, especially in the early stages of pregnancy.

You cannot be in the study if you are breastfeeding. It is not known whether the study drug is safe for breast fed babies. Therefore if you are breastfeeding a child then it may not be safe for you to participate in the study.

If you are a man, it is suggested that you use birth control if you choose to have sex with women while in this study. You must also not donate sperm during the study and for at least 4 weeks after completion of the study.

POSSIBLE BENEFITS OF THE STUDY

There is no promise that your condition will get better. It might stay the same or it might get worse. You will be closely monitored. If your condition becomes worse or dangerous to your health, your doctor may stop your participation in this study. The study doctor will treat you as he/she feels is best.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

This study is for research only, but the treatment given may be effective for your condition. The study drug is approved by the FDA for other skin conditions and is available with a prescription. If you are interested in the study drug or any other treatment for your acne vulgaris, you should discuss discus your options with your normal physician or dermatologist outside of this study. Treatments including benzoyl peroxide and salicylic acid creams and gels may be purchased without a prescription to treat acne.

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CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The investigator
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- The United States Food and Drug Administration (FDA)
- Other state or federal regulatory agencies
- IntegReview IRB

A description of this clinical trial will be available on 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.

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

IN CASE OF STUDY RELATED INJURY

No compensation will be offered by the site or sponsor in the event of a study-related injury. If you are given treatment for any injury by the site, you or your insurance may be billed for the cost of that treatment. No other form of compensation will be offered.

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Leon Kircik, M.D.
Daytime telephone number: 502-451-9000
After-hours number: 502-396-5310

If you are unable to reach anyone at the number(s) listed above and you require immediate (life threatening) medical attention, please go to the nearest emergency room.

If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

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Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You may receive up to $500.00 for being in the study. You will be paid per completed visit as follows:

Visit	Compensation (amount)
Visit 1 / Screening Only	$100.00
Visit 2 / Baseline (Week 0)	$100.00
Visit 3 (Week 4)	$100.00
Visit 4 (Week 8)	$100.00
Visit 5 (Week 16)	$100.00

If you choose to leave or are withdrawn from the study for any reason before finishing all visits you will be paid for each completed visit. You will receive payment within 4 weeks after your last study visit, or if you choose to leave or are withdrawn from the study for any reason, you will receive payment within 4 weeks after you officially withdraw.

You may be required to report the payment received for this study to the Internal Revenue Service as taxable income.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled. You can still get healthcare in the future.

The investigator (study sponsor), IntegReview, or certain regulatory groups (like the FDA) may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the investigator's instructions
- If we find out you should not be in the study

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JUNE 12, 2017**

- If the study is stopped
- If it becomes harmful to your health

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?
The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well-being of the human subjects participating in research studies.

IntegReview, the IRB for this study
IntegReview is an IRB whose board members provide IRB services across the United States, Latin America and Japan.

To meet requirements of the law, the IntegReview Boards currently include:

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science/medicine

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AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

I. Do you know that you cannot be in another study while you are in this study? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS, OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS, YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

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The signature lines below are required when minor subjects are involved.

_____
Printed Name of Minor Study Subject

_____
Printed Name of Parent, Guardian or Legally Authorized Representative

_____
Signature of Parent, Guardian or Legally Authorized Representative Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You (and/or your legally acceptable representative) will receive a signed and dated copy of this consent form to keep.

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ASSENT FORM FOR MINOR STUDY SUBJECTS

12 – 17 years of age

You are being asked to be in a research study about your acne. A research study is a way to learn more about the study drug and its uses.

If you decide that you want to be a part of this study, you will be asked to come to the site up to 5 times for about 1-2 hours each visit and you will be asked to put study drug on your face daily for about 4 month. This study will last between 4 and 5 months.

There are some things about this study that you should know. At each study visit:

- The study doctor will look at your face and count your pimples
- You will complete assessments and answer questions about your condition

Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. We think these benefits might be fewer dark spots from acne on your skin.

Some people find that the study drug may make their face feel sore or irritated. You may find this or you may not.

If you do not want to be in this research study, we will tell you what other kinds of treatments there are for you.

When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.

You do not have to be in this study if you do not want to be. You can say no and no one will be mad at you. If you decide to stop after we begin, that's okay too.

Statement of Assent:

I have read or someone has read to me this assent form. My parent(s) or my legally authorized representative (if applicable) and the investigator have explained the study to me and have answered my questions. I agree to be in this study.

_____
Printed Name of Minor Study Subject

_____
Signature of Minor Study Subject Date

_____
Printed Name of Person Explaining Assent Form

_____
Signature of Person Explaining Assent Form Date

You (and/or your legally acceptable representative) will be given a signed and dated copy of this consent form to keep.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL
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