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Wake Forest™
School of Medicine

Department of Dermatology

ORAL PSORIASIS TREATMENT ADHERENCE AND INTERVENTION STUDY

Informed Consent Form to Participate in Research
William W. Huang, MD, MPH, Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have moderate to severe psoriasis and have been prescribed oral methotrexate therapy. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to evaluate patients' experiences with oral psoriasis treatment. Subjects will be surveyed at different frequencies to determine their experiences.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

There will be approximately 40 subjects enrolled in this study. This study is only being conducted at Wake Forest University Health Sciences in the Department of Dermatology.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the study groups. Randomization means that you are put into a group by chance. One study group will receive emailed surveys to complete; the other study group will not receive the email surveys. It is like flipping a coin. You will have an equal chance of being placed in either group. The investigator will not know if or at what frequency you are receiving the Internet survey. This is done so that a fair evaluation of results can be made. This information is available to the researchers if needed in an emergency.

If you agree to enroll in this study, you will be asked to read and sign this consent before any study-related procedures are performed. You cannot take any systemic psoriasis medication in addition to methotrexate while participating in this study. You will be asked to come to the study center four times. At these visits the following procedures will be done:

Screening/Baseline Visit:

- You will provide written informed consent in order to participate in the study.
- You will provide information, such as address, telephone number, birth date, gender, and emergency contact information. This information will be used for study purposes and will not be used outside of the reasons discussed in this Informed Consent.
- You will be asked to provide information regarding your medical and surgical history, as well as smoking and drinking habits. In addition, information regarding your prior and current medications will be reviewed.
- The doctor or study staff will perform a limited physical exam
- The doctor and/or study staff will complete an assessment of your skin.
- If you are using another systemic medication for psoriasis in addition to methotrexate, you may have to stop this treatment.
- You will be given directions to take the study medication as prescribed by your dermatologist.
- You will be randomized to a study group. The frequency to which you receive the survey will depend on the group you are assigned.
- You will be provided the study medication, oral methotrexate.
- You will be asked to return the study center in one month with the medication jar.
- If you run out of medication before your next visit, you should call the study center to have your prescription refilled. You should bring your empty medication jar to the study center. A study staff will refill the medication.
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Month 1:

- Study staff will review any changes in your general health, any new medications that you may have taken, and any adverse events to the study medication.
- The doctor and/or study staff will complete an assessment of your skin to determine whether the oral methotrexate therapy has improved your psoriasis.
- Your medication jar will be collected, weighed, and returned to you.
- You will be asked to return the study center in two months with the medication jar.
- If you run out of medication before your next visit, you should call the study center to have your prescription refilled. You should bring your empty medication jar to the study center. A study staff will refill the medication.

Month 3:

- Study staff will review any changes in your general health, any new medications that you may have taken, and any adverse events to the study medication.
- The doctor and/or study staff will complete an assessment of your skin to determine whether the oral methotrexate therapy has improved your psoriasis.

- Your medication jar will be collected, weighed, refilled, and returned to you.
- You will be asked to return the study center in three months with the medication jar.
- If you run out of medication before your next visit, you should call the study center to have your prescription refilled. You should bring your empty medication jar to the study center. A study staff will refill the medication.

Month 6 (End of the Study or Early Termination Visit):

- Study staff will review any changes in your general health, any new medications that you may have taken, and any adverse events to the study medication.
- The doctor and/or study staff will complete an assessment of your skin to determine whether the oral methotrexate therapy has improved your psoriasis.
- Your medication jar will be collected to be weighed.
- If you were randomized to receive the internet survey, you will complete an Exit Interview to share your feedback on the survey.
- You will complete a survey on your satisfaction with the medication treatment and a survey regarding physician trust.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 6 months. You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Methotrexate is a FDA approved medication commonly used to treat moderate to severe psoriasis. Risks and side effects related to the oral methotrexate therapy include, but are not limited to, nausea, anorexia, fatigue, and inflammation or ulcerations of the mouth and lips (stomatitis).

Methotrexate can cause myelosuppression. This means decreased production of cells that provide immunity (white blood cells), carry oxygen (red blood cells), and/or enable the blood to clot (platelets). Your dermatologist will closely monitor for low blood cell counts at your regular clinic follow-up visits. Risk of myelosuppression is decreased by taking folate supplements as directed by your dermatologist.

Methotrexate can affect the liver. For this reason, you will be asked to abstain from excessive alcohol intake while on oral methotrexate therapy. Your dermatologist will monitor your liver function at regular clinic follow-up visits. One side effect of methotrexate toxicity is developing scarring of the lung tissue (pulmonary fibrosis). Notify your physician if you develop any new pulmonary symptoms, such as cough, while taking methotrexate.

Methotrexate can cause fetal malformation (teratogenic) and induce fetal death (abortifacient).
If you are a woman of childbearing age and are sexually active, you will be instructed to use reliable method of birth control while on this medication. Reliable methods of birth control are:

abstinence (not having sex), oral contraceptives, intrauterine device (IUD), Depo-Provera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a cervical cap or sponge. We encourage you to discuss this issue further with your physicians if you have any questions. Should any additional side effects of this study medication be identified while you are in the study, you will be notified.

As far as unanticipated risks, this study involves an oral medication that is routinely used in dermatologic conditions and approved by the FDA for treatment of psoriasis. The risks are limited and listed above. However, all drugs have a potential risk of an allergic reaction, which, if not treated properly, could become life threatening.

There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be:

Subjects may benefit from improvement in their condition through participation in this study. Psoriasis that is not treated can lead to further development of erythematous papules and plaques with a silver scale. Subjects will also be seen regularly for visits and may gain more information about management of their disease.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you could be treated with oral methotrexate even if you do not take part in the study.

What About My Health Information?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** medical history, prior and current medications, and allergies. It also includes demographic information such as name, address, date of birth and social security number.

If this research study involves the diagnosis or treatment of a medical condition, then Protected

Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

3) Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state law.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Huang that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

William W. Huang, MD, MPH
Department of Dermatology
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research

study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

By signing this form you give us permission to use your Protected Health Information for this study.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study costs, including any procedures related directly to the study, will be paid for by the study. Costs for your regular medical care will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid $100 if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion you will be paid $25 for each complete study visit.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Sciences (WFUHS). Pfizer is providing support to conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor. WFUHS has applied for a patent for electronic survey programs and has started a company to provide such services.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Huang at [redacted] or after hours through the hospital operator at [redacted].

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact Dr. Huang at [redacted] or after hours through the hospital operator at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect

your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted].
You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (printed):_____

Person Obtaining Consent Signature: _____ Date:_____ Time:_____ am pm