University Hospital Medical Center

This is a fictional consent form based on actual documents.

Date:

_____

Patient's name:

_____

Operation and/or procedure to be performed:

_____

1. I hereby authorize Dr. _____ or associates or assistants of his/her choice at University Hospital Medical Center to perform upon me or the above named patient the following operations and/or procedures.

2. Dr. _____ has fully explained to me the nature and purposes of the operation/procedure and has also informed me of expected benefits and complications (from known and unknown causes), attendant discomforts and risks that may arise. I have been given the opportunity to ask questions, and all of my questions have been answered fully and satisfactorily.

3. I understand that during the course of the operation and/or procedure, unforeseen conditions may arise that necessitate procedures different from those mentioned above. I consent to the performance of additional operations and/or procedures which the above named physician or his/her associates or assistants may deem necessary.

4. Any tissues surgically removed may be retained by the Hospital for medical, scientific, or educational purposes.

5. Signing this document means that the treatment and/or procedure, including the above information, has been described to me orally in a language that I understand and that I voluntarily consent to such treatment and/or procedure.

6. I confirm that I have read and fully understand the above and that all of the blank spaces have been completed prior to my signing.

7. I consent to have images, pictures, or other representations of me and/or tissues that may be taken to be used for educational, medical, or promotional materials by University Hospital.

Patient/Relative or guardian:

_____ Signature

_____ Print name

_____ Date and time

Relationship, if signed by person other than patient:

_____

*The signature of the patient must be obtained unless the patient is an unemancipated minor under the age of 18 or is incompetent to sign.

Consent Form 2

Authorization for Surgery and/or Special Procedure/Treatment

[this is a fictional consent document, based on real examples]

Patient's Name: _____

I hereby authorize Dr._____ to perform the following surgery and/or special procedure/treatment:

Aortic Valve Replacement Mitral Valve Reconstruction, Replacement

Tricuspid Valve Reconstruction, Replacement Closure Ventricular Septal Defect

Replacement of Ascending Aorta MAZE Procedure Coronary Artery Bypass

Cardiopulmonary Bypass Insertion of Intra Aortic Balloon Pump

Ventricular Assist Device Insertion Intraoperative TEE

I understand that residents, medical students, physician assistants and/or advanced practice registered nurses may also be in attendance, and/or assisting in the performance, and/or performing significant medical/surgical tasks within the above specified surgery and/or special procedure/treatment. I also understand that there may be unforeseen circumstances that are encountered while performing the above listed surgery and/or special procedure/treatment that require the assistance of other qualified medical personnel who have not been identified.

I have had explained to me in connection with the proposed surgery/procedure/treatment: (i) the nature and purpose of the proposed surgery/procedure/treatment; (ii) the foreseeable risks and consequences of the proposed surgery/procedure/treatment; (iii), the alternatives to the proposed surgery/procedure/treatment and the associated risks and benefits to such alternatives; and (iv) the reasonably foreseeable risks and alternatives to the transfusion of blood and blood products should I need a blood transfusion.

Specifically, in obtaining my informed consent to the surgery and/or special procedure, I have been informed of the following reasonably foreseeable risks, including, but not limited to:

Heart Attack Infection Bleeding Stroke

Kidney injury/failure requiring dialysis Allergic reaction to X-ray dye or medications

Introduction of air into the blood stream Tear of a cardiac chamber or vessel

Bruising at the site of catheter Skin reaction from X-ray equipment

Heart valve damage Peripheral nerve injury Liver failure

Death Heart Failure Requiring Advanced Circulatory Support

Respiratory failure requiring prolonged ventilation and/or tracheostomy

Blood vessel damage including bleeding, vessel perforation, the need for elective emergency surgical repair, infection, limb ischemia (requiring surgery or loss of limb)

Patient initial _____

I am aware that, in addition to the reasonably foreseeable risks described, there are other foreseeable risks, which have been discussed with me, but are not listed. I affirm that I understand the purpose and potential benefits of the proposed treatment and/or special procedure, that no guarantee has been made to me as to the results that may be obtained, and that an offer has been made to me to answer any of my questions about the proposed surgery/procedure/treatment.

I also authorize the Hospital and the above-named physician(s) to photograph, video and /or use any other mediums which result in the permanent documentation of my image for medical, scientific or educational purposes, provided my identity is not revealed by them.

_____ M.D. Date: _____ Time: _____

_____ Signed Date: _____ Time: _____

(Patient or legally authorized representative)

Interpreter responsible for explaining procedures and special treatment:

_____ Date: _____ Time: _____

(Interpreter)

PATIENT UNABLE TO SIGN PRIOR TO SURGERY BECAUSE:

_____

_____ M.D. Date: _____ Time: _____

Informed Consent to Participate in a Clinical Research Study

THIS DOCUMENT IS A FICTIONAL EXAMPLE OF A TYPICAL INFORMED CONSENT FORM.

Study Title:	A Phase II, Randomized, Double-Blind, Dose-Ranging Study of the Treatment of Alopecia of the Scalp with Headstart (Capsaicin) Patch
Sponsor:	Headstart Pharmaceuticals, Inc.
Protocol Number:	HSP03
Protocol Date:	June 16, 2004 (Version 1 .0)
Principal Investigator:	Seldon Heer, M.D. Heer Hair Clinic, Inc.

INTRODUCTION

This document may be difficult to understand in places. Please ask questions if there are parts you do not understand.

Your participation in this research study is voluntary and you may withdraw at any time, for any reason. If you choose not to be in the study, you will not lose any medical benefits and you can still participate in future studies.

This document contains information about the study, explains the risks of being in the study, and explains your role and responsibilities as a participant. Please read it carefully and feel free to ask any questions you may have.

BACKGROUND

This is the first study of the HeadStart patch for treatment of alopecia of the scalp. No animal studies have been performed because there are no suitable animal models. This study was initiated based on observed local hair growth in a clinical study of tinea pedis ("athlete's foot"), where capsaicin was evaluated as an adjuvant (stimulating ingredient).

DESCRIPTION AND PURPOSE OF STUDY

You are being asked to participate in this study because you have been diagnosed with alopecia (hair loss) of the scalp. The purpose of this study is to determine if an experimental "study drug," a patch containing capsaicin, is safe and effective when given to people with your condition. An experimental drug is one that has not received approval by the U.S. Food and Drug Administration (FDA).

Capsaicin is a man-made version of a peppery substance found in chili peppers. Low-concentration capsaicin creams and patches are available without prescription for controlling pain from arthritis (swelling of the joints), back pain and painful muscle soreness. However, it is

unknown if the experimental patches containing 10 to 20 times higher concentrations of capsaicin will be helpful in reversing alopecia. It is also unknown if any hair growth that results from treatment will be temporary or permanent.

INITIAL VISIT

If you qualify for the study, you will come in for two visits. At the first visit, we will measure your vital signs (blood pressure, heart rate, breathing rate and temperature), perform a physical exam, photograph your scalp, and take your medical history. We will collect a blood sample to measure the level of harontin in your blood. Harontin is a natural hormone associated with hair growth. We will collect approximately 2 tablespoons of blood. You will be asked to rate any discomfort or pain you have before, during and after the study patch application.

We will shave the balding area of your scalp. We will place a study patch in this area for 10 minutes. You will receive either the high or low dosage patch. You may request Oxycodone, a narcotic pain medication, before application of the patch. This medication may lessen any discomfort you might have. After the patches are removed, we will shampoo and massage your scalp.

We will ask you, for the 14 days following your visit, to complete a diary about the condition of your scalp where the study patch was applied. If you notice changes in your hair or skin, please call the study coordinator. We will also ask you to record your level of pain, if any, every evening. You will score the pain on a scale of 0 (none) to 10 (the worst you have ever felt).

FOLLOW-UP VISIT

After 14 days, you will come in for a follow-up visit. We will examine the treated area of your scalp, measure hair growth, if any, and test your ability to feel various sensations in that area. We will photograph your scalp again.

We will collect another blood sample of approximately 2 tablespoons to measure the change in the level of harontin, if any, in your blood.

FOLLOW-UP TELEPHONE CALLS

After the follow-up visit, we will call you monthly for 12 months to ask you about any changes in your hair or scalp. During this period, we will ask you to collect any hair clippings from the treated area in plastic bags that we will provide to you, and mail those clippings to us in postage-prepaid envelopes that we will provide to you. If you notice changes in your hair or skin during this period, please call us.

FINAL VISIT

After the follow-up telephone calls are complete, you will come in for a final visit. We will examine the treated area of your scalp, measure hair growth, if any, and test your ability to feel various sensations in that area. We will also shave the treated area of your scalp and weigh the hair. We will collect another blood sample of approximately 2 tablespoons to measure the change in the level of harontin, if any, in your blood.

EARLY TERMINATION

If you choose to stop or the investigator stops your participation for any reason, you will either be asked to undergo a final evaluation or be contacted by phone or certified mail. Your response is important for your health and safety.

RISKS AND DISCOMFORTS

You must tell the investigator about any health problems you have while you are taking part in this study. Giving false, misleading or incomplete information about your medical history, including past and present use of other medications or recreational drugs, or alcohol, could affect your well-being while taking part in this study

The study drug, capsaicin, may cause mild to moderate warmth, stinging, burning sensation or pain, swelling, redness, numbness or peeling in the application area. On rare occasions, it has caused a moderate or severe allergic reaction. Allergic reactions could include swelling, rash, hives, difficulty breathing, and shock.

Any hair that grows in the application area may not have the same color or texture as your other hair. It will certainly appear different than any surrounding bald or balding area of your scalp.

There may be pain, swelling, or bruising around the vein where your blood is drawn. You may feel dizzy or you may faint. Infection at the blood-drawing site also may occur.

Side effects of the pain medication (Oxycodone) may include lightheadedness, dizziness, sedation, nausea, vomiting, constipation, headache, slowed breathing, itching and rash.

If you touch the treated area of your scalp before we shampoo it, hair may grow on your hands, and parts of your body that your hands touch.

You will be informed of any significant new information that could affect your willingness to continue to participate in the study

Should you develop any side effects, please report them to us. We can be reached at at any time. In addition, should you withdraw from the study for any reason, we will attempt to contact you by telephone or certified letter (if needed), to ask about your health.

PREGNANCY

The potential for this investigational drug to affect a human pregnancy is unknown. If you are a woman, you should not participate unless you are post-menopausal, are surgically sterile, or agree to use effective birth control. Pregnant women will not be allowed to participate in this study. If you become pregnant during the study, contact your doctor immediately and you will be withdrawn from the study. If you are male, you should take effective birth control precautions with your partner to ensure that she does not become pregnant for the duration of the study.

Please discuss the method of birth control you will use with the investigator to be sure it is effective.

BENEFITS

The ability of high-dose capsaicin patches to grow hair is not yet known.

You and society may benefit from this clinical research study. Such benefits include the possibility that your alopecia may improve and that the study may help develop a new therapy for others with similar conditions.

PAYMENT

You will be paid a maximum of $150.00 for your participation -- $50.00 for each of the three visits.

NEW FINDINGS

You will be told about any significant new findings that may affect your willingness to participate in the study.

ALTERNATIVES

You may choose not to participate in this study.

You do not have to participate in this study to receive treatment for your condition. Other medications have been used to grow hair. The investigator will describe the potential benefits and risks of alternative procedures or courses of treatment.

COST

You will receive the study drug, office visits, lab tests, and procedures at no cost.

INVESTIGATOR PAYMENT

The sponsor is paying the investigator for conducting the study.

COMPENSATION FOR INJURY

If you become injured as a direct result of a study procedure, the investigator will provide reasonable medical treatment. Headstart Pharmaceuticals will pay the cost of this treatment, to the extent it is not covered by your health insurance. Headstart

Pharmaceuticals will not be responsible for any other treatment costs or for your regular medical care.

You are not waiving any legal right to seek additional compensation through the courts.

PARTICIPATION

We may remove you from the study without your consent for any of the following reasons: (1) if the investigator decides that continuing the drug will be harmful to you, (2) if you fail to keep appointments or to complete the diary, (3) if you have a serious reaction to the study patch, or (4) if the sponsor or the Food and Drug Administration (FDA) stops the study.

Your participation in this research study is completely voluntary. You can choose to withdraw from the study at any time. If you withdraw or are withdrawn from the study, you will not be harming your relationship with the investigator.

CONFIDENTIALITY

All or part of your medical records may be reviewed by the Food and Drug Administration (FDA), other national health authorities (where applicable), and representatives of Headstart Pharmaceuticals, Inc. Care will be taken to maintain the privacy and confidentiality of your records.

Information from this study may be published in scientific journals or presented at scientific meetings. Your identity will be kept strictly confidential

As stated in the section below entitled Consent, you can refuse to sign this consent authorization and not be part of this study. You can also tell us you want to leave the study at any time without canceling the authorization.

By signing this consent form, you give us permission to use and/or share your health information as stated above.

CONSENT

I have read this consent form. I also have discussed it with the investigator to my satisfaction. I understand that my taking part is voluntary. I know enough about the purpose, methods, risks and possible benefits of the study to decide that I want to take part in it, and I know that I can call the investigator if I have any questions or side effects.

I do not know of having any medical condition that would prevent me from taking part in the study. I agree to participate in the study.

_____	_____	_____
Date	Subject's Signature	Printed Name
_____	_____	_____
Date	Signature of Person Obtaining Consent	Printed Name
_____	_____	_____
Date	Witness Signature	Printed Name

PHYSICIAN STATEMENT

In addition to advising the above study participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study, and to answer any further questions relating to it.

_____
Signature of Investigator

_____
Printed Name of Investigator

_____
Date