

# HeadStart Pepperpatch

## Clinical Research Study Informed Consent Form

**Y**ou have been asked to take part in a clinical study of HeadStart PepperPatch, an experimental treatment for growing hair.

Before you write your name below, first read the rest of this form. Ask any questions you might have. Then read and check the following statements:

- I have read the whole consent form.
- All of my questions have been answered to my satisfaction.
- The correct answers to the questions on page 10 have been explained to me.
- I know that joining the study is voluntary.
- I know enough about the purpose, methods, risks and possible benefits of the study to decide that I want to join it.
- I know that I can call the investigator if I have any questions or possible side effects.
- I do not know of any medical condition that would prevent me from joining the study.
- I agree to join the study.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Subject or Representative

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Printed Name

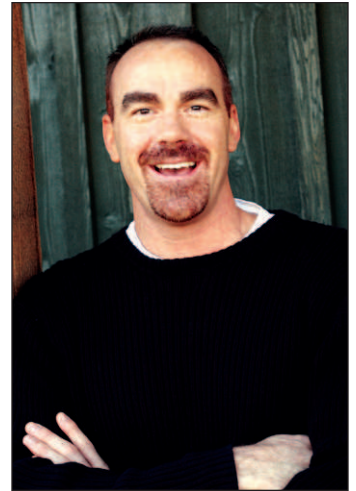
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Date

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Witness Signature

\_\_\_\_\_  
Printed Name

# Why you might want to take part in this clinical study

- If the treatment works, you might grow new hair.
- You will receive the study drug, office visits, lab tests, and procedures at no cost.
- You may help other people with hair loss.
- We will pay you \$150 for taking part in the study, \$50 for each of three visits.



## About HeadStart Pepperpatch

- HeadStart PepperPatch uses capsaicin, a man-made substance like that found in chili peppers.
- Creams and patches with low levels of capsaicin are used to treat arthritis pain, back pain, and muscle pain.
- A high level of capsaicin causes hair to grow on feet when used to treat athlete's foot. We want to find out if it will also grow hair on the top of the head.
- We also want to know whether new hair growth will be temporary or permanent.
- We also want to know if the treatment is safe and does not cause unacceptable side effects.

Have a question? Write it here:

My question has been answered.

I've read this page.

 Initial: \_\_\_\_\_

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# 1. Your First Visit

**?** Do you remember...  
what capsaicin is used to treat now?

At your first visit, we will:

- Measure your vital signs—blood pressure, heart rate, breathing rate, and temperature.
- Perform a physical exam.
- Photograph your scalp.
- Take your medical history.
- Collect about 2 tablespoons of blood to measure the level of harontin in your blood. Harontin is a natural hormone associated with hair growth.
- Shave the balding area of your scalp.
- Give you an Oxycodone pill to reduce discomfort — if you request it.
- Place a study patch on your scalp for 10 minutes. You will receive either the high or low dosage patch.
- Remove the patch.
- Shampoo and massage your scalp.



**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.**

We will ask you to rate any discomfort or pain you have before, during and after the study patch application.



**The Headstart Pepperpatch**

## Caution!

**Giving false or incomplete information about your medical history or the use of drugs or alcohol could affect your health while in this study.**

Have a question? Write it here:

My question has been answered.

I've read this page.

 Initial: \_\_\_\_\_

HSP03 Consent Form Version 1.0

## 2. After Your First Visit

**? Do you remember...**  
what the Oxycodone pill is for?

During the 14 days following your visit, you will keep a journal about the condition of your scalp where the study patch was applied.

**If you notice changes in your hair or skin, also call your study coordinator.**

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).



**Keep careful records between visits**

## 3. Your Second Visit



After 14 days, you will come in for a follow-up visit. We will:

- Examine the treated area of your scalp.
- Measure the hair growth.
- Test your sensations in that area.
- Photograph your scalp again.
- Take another blood sample of about two tablespoons to measure any change in the level of harontin in your blood.

Have a question? Write it here:

My question has been answered.

I've read this page.

 Initial: \_\_\_\_\_

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## 4. Follow-Up Phone Calls

**?** Do you remember...  
what you do between visits?

After the follow-up visit, we will call you monthly for 12 months to ask about any changes in your hair or scalp.

Collect any hair clippings from the treated area in the plastic bags that we will give you. Mail the clippings to us in the postage-paid envelopes provided.

**If you notice changes in your hair or skin during this period, please call us.**



## 5. Your Third Visit



After 12 months, you will come in for your final visit. We will:

- Examine the treated area of your scalp.
- Measure any hair growth.
- Test your sensations in the treated area.
- Shave the treated area of your scalp and weigh the hair.
- Collect another blood sample of about two tablespoons to measure any change in the level of harontin in your blood.

Have a question? Write it here:

My question has been answered.

I've read this page.

 Initial: \_\_\_\_\_

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# Why you might not want to take part in this clinical study

**?** Do you remember...  
when the final visit is?

You may choose not to join this study. You will not lose any medical benefits and can still join future studies.

You do not have to join this study to receive treatment for your hair loss. There are other treatments available to grow hair.

The investigator will describe other treatments and their risks and benefits.

This is the first study in humans (or animals) of the HeadStart PepperPatch for growing hair.

Treatment patches contain 10 to 20 times more capsaicin than is used to treat other conditions.

We will keep you informed about any new information that might affect your decision to take part in this study.

## Pregnancy

We do not allow pregnant women to join this study. We don't know what effects the HeadStart PepperPatch has on pregnancy.

If you are a woman, you should not join this study unless:

- You have passed menopause,
- You are sterile, or
- You agree to use birth control.

If you become pregnant during the study, contact us immediately and withdraw from the study.

If you are a man, you must practice birth control to prevent partner pregnancy during the study. We will discuss the method of birth control you will use to be sure it is effective.



Have a question? Write it here:

My question has been answered.

I've read this page.

 Initial: \_\_\_\_\_

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# Risks and Discomforts

**? Do you remember...**  
are other treatments available to grow hair?

- We do not know if the treatment will grow new hair on your head.
- In nine cases out of ten, the study drug causes mild to moderate warmth, stinging, a burning sensation, pain, swelling, redness or numbness. In one case out of 100, it causes peeling in the patch area.
- In one case out of 1,000, it causes an allergic reaction. Allergic reactions may include swelling, rash and hives. In one case out of 10,000, it has caused difficulty breathing or shock.
- We do not know if any hair that grows in the area of the patch will 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. In one case out of 40, there is pain, swelling or bruising around the vein where blood is drawn. In one case out of 80, dizziness or fainting occurs.
- In one case out of 1,000, infection at the blood-drawing site occurs.
- The pain medication Oxycodone can cause lightheadedness, dizziness, sedation, nausea, vomiting, constipation, headache, slowed breathing, itching or rash. In one case out of four, the effect is mild. In one case out of 20, the effect is moderate. In one case out of 200, the effect is severe. In the other cases, there is no effect.



We will inform you of any new information that might cause you to drop out of the study.

**If you develop any side effects, report them to us at (437) 342-4763 at any time.**

## Medical conditions?

**Tell the investigator if you experience any health problems during the study.**

Have a question? Write it here:

My question has been answered.

I've read this page.

 Initial: \_\_\_\_\_

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# Compensation for Injuries

**? Do you remember...**  
can the treatment cause a rash?

If you are injured as a direct result of a study procedure, HeadStart Pharmaceuticals will cover any treatment costs not paid by your health insurance. It does not plan to pay for any other treatment costs or for your regular medical care.

**If you are injured, you have the right to seek compensation through the courts.**



## Leaving the Study

Joining this study is completely voluntary. You can leave the study at any time.

We may remove you from the study for the following reasons:

- The investigator decides that the study will harm you.
- If you fail to keep appointments or to complete the journal.
- If you have a serious reaction to the study patch.
- If HeadStart Pharmaceuticals or the Food and Drug Administration (FDA) stops the study.

If you choose to stop or the investigator asks you to stop, we will ask you to come in for a final evaluation, or we contact you by phone or certified mail. Your response is important for your health and safety.

Have a question? Write it here:

My question has been answered.

I've read this page.

 Initial: \_\_\_\_\_

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# Privacy—Your Medical Records

**?** Do you remember...  
when you can leave the study?

In signing this consent form, you give access to your medical records to:

- Heer Health Clinic
- The Food and Drug Administration (FDA) and other national health authorities
- Representatives of HeadStart Pharmaceuticals

We will protect the privacy of your records. We may publish this study in scientific journals. We may present it at scientific meetings. If we do, we will keep your identity strictly confidential.



## Questions About Your Rights?

If you have any questions about your rights as a research subject, contact:

Medical Chairman  
Acme IRB  
P.O. Box 12345  
Palo Alto, CA 94301

You can also call toll free: (888) 472-1234 Monday to Friday from 9 to 5 p.m.

Have a question? Write it here:

My question has been answered.

I've read this page.

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# More Information

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STUDY TITLE: A Phase II, Randomized, Double-Blind, Dose-Ranging Study of the Treatment of Alopecia of the Scalp with PepperPatch (Capsaicin) Patch

SPONSOR: HeadStart Pharmaceuticals, Inc.

PROTOCOL NUMBER: HSP03

PROTOCOL DATE: June 16, 2006 (Version 1 .0)

PRINCIPAL INVESTIGATOR: Seldon Heer, M.D.  
Heer Hair Clinic, Inc.

## Have We Covered Everything?

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To make sure we have explained the study to you, answer these questions:

- The study patch contains a substance like that found in \_\_\_\_\_.
- I will come in for \_\_\_\_ visits over \_\_\_\_ months.
- I will be paid \$\_\_\_\_\_ for each visit.
- I can drop out of the study when \_\_\_\_\_.
- A common risk of the treatment is \_\_\_\_\_.

If you are not sure of your answers, or if you have any other questions, please ask.

You can also call us at (437) 342-4763 if you have any other questions about the study, your rights as a research subject, the procedures, risks or benefits, or about an injury from the study.

Have a question? Write it here:

My question has been answered.

I've read this page.

 Initial: \_\_\_\_\_

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# Investigator's Statement

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- I confirm that the Subject has signed this consent form.
- I have explained other treatments for hair loss to the Subject.
- I have explained the risks and discomforts associated with the study.
- I have given the Subject a good opportunity to ask questions about the study and I have answered them.
- I know of no reason why the Subject should not join the study.

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Signature of Investigator

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Printed Name of Investigator

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Date