



CAPS INC.  
123 MEADOW WAY  
VERDANT, CA

123-456-7890  
F: 123-456-7891  
capsinc@something.com

**CONSENT TO BE A RESEARCH SUBJECT**

**A Novel Hatarectomy Device – Does it work?**

*There is no rule that the full incomprehensible title must be used. The title should be in lay language.  
Put the protocol ID in the footer.*

**PART I - INFORMATION ABOUT BEING IN ANY RESEARCH STUDY**

Being in a study is different from being a patient. As a patient, the doctor’s focus is on you. As a subject, the investigator must also follow the rules of the study. Those rules and your individual needs may come into conflict. In the event of a conflict, the study doctor’s first responsibility is for your safety and welfare.

This consent form describes the research study and your role as a participant. Please read this form carefully. Do not hesitate to ask anything about the information provided; it should stimulate your questions. The doctor or nurse will describe the study and answer your questions.

**PART 2 – INFORMATION ABOUT THIS STUDY**

**A. BACKGROUND AND PURPOSE**

*This section should give some idea about why the study is being done and give an idea about the "research" objectives. After reading this section, the procedures and goals should make sense. It should include an invitation.*

*The purpose is to answer some question; it is not to assist an individual. This section should have no personal pronouns.*

The current treatment for Green Hat Syndrome is a hatarectomy; that is, a hat removal procedure. This is usually done using a device called a Haterizer. The problem with current haterizers is that they come in only one size.

Caps, Inc. is studying whether their investigational haterizer, "Ex-Hat" will perform well on people of all sizes. This study will compare the use of the Ex-Hat with the Haterizer using people with Green Hat Syndrome.

*It is also possible to put in explanations of the test article or of the history of the development.*

**B. PROCEDURES**

Participating means being at the Caps Inc. offices for two hours a day for three days or until your Green Hat is removed once by each device. By the conclusion of the study you should be completely dehatted.

The choice of which device is used first each day will be made randomly; that is, you will have a 50% chance of being assigned to the Ex-Hat or the Haterizer each day and neither the investigator nor you will make that choice.

In order to participate in this study it is important not to risk becoming pregnant. Women will have a urine pregnancy test before the first day and both men and women must agree to use a barrier form of

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contraception for intercourse for up to 7 days after participation in the study is completed. *(Contraceptive requirements are procedures.)*

As haterizers react to the smell of coffee before 11:00 AM, it is important that no person enter the room with Coffee-breath. All participants must agree to abstain from coffee for 24 hours before participation.

Day 1 - 9 AM - stop all caffeine

Day 2, 3, and 4 Arrive at 9:AM - 3 hours of removals - Leave by noon

*This section should provide a simple overview of the experience of being a subject as compared to the experience of being a patient.*

*A picture of the haterizer could be inserted here.*

*Anything that is experimental or investigational should be noted as such.*

*Chronological explanations help. Calendars, pictures and charts help.*

*Ancillary procedures such as male and female contraception requirements should be mentioned as should abstinence from drugs (licit or illicit), caffeine or sex.*

**C. POSSIBLE RISKS OR DISCOMFORTS**

*This section should include an explanation of what a potential subject needs to know to make an "informed" decision. It should include serious risks and their frequency and common events and their magnitude.*

1. Caffeine withdrawal can cause headaches.
2. It is possible for the haterizer or the Ex-Hat to miss the Green Hat and remove something at an inappropriate level on your body. This could provide some

embarrassment. A fail-safe switch is provided for you to use should that happen. As this is the first use of the Ex-Hat with humans, there might be some other problems that are as yet unknown.

3. For some unknown reason, the makers of the device believe that it could cause fetal malformations and they don't know whether it is a problem with egg or sperm. Please do not even think about getting pregnant or getting anyone pregnant.

*Subjects may be concerned with legal, emotional financial and logistical harms as well. The risk of loss of privacy and financial harms should be discussed.*

4. Many people are embarrassed about their Green Hat Syndrome and arriving at Caps, Inc. could reveal your need for a hatarectomy. You may drive to the back and enter through the staff entry.

5. Privacy and confidentiality:

*No absolute promises or guarantees of confidentiality may ever be made unless the investigator is willing to go to jail to protect his or her sources.*

Your identity will be maintained as confidentially as is possible within the limits of the law. However, auditors from Caps, Inc., and the Food and Drug Administration and from a research review committee have the right to inspect all records (medical and research) that relate to this study. No scientific reports by the investigator or the company will use any identities.

There is more information about privacy on the attached Authorization form. *(We prefer separation of consent and authorization.)*

Pictures will be taken which may be published in a later report. No

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identifiable pictures will be published without specific consent from you.

What happens if one of the harms actually occurs?

If you are injured as a result of participating, you will be treated appropriately. The cost of that treatment may be covered by Caps, Inc or by the investigator. Neither is agreeing to cover any non-medical costs. For more information on the Caps, Inc. policy you may call the Medical Director at (xxx) xxx-xxx. You are not giving up any of your legal rights.

*This section is required IF there is more than minimal risk. There must be "an explanation as to whether any compensation and as to whether any medical treatments are available " and if so, "what they consist of or where further information may be obtained."*

**D. POSSIBLE BENEFITS**

There will probably be no benefit to you from participating. Other people with Green Hat Syndrome might benefit if a better device reaches the market someday.

*Realistic benefits or outcomes to individuals should be stated. Financial compensation is not a benefit and should be mentioned below.*

**G. QUESTIONS**

There are a variety of people available to you.

Type of question	Role	Person	Contact
About the study, procedures risks, benefits, alternatives and rights	Investigator	Dr. Chapeau	Phone (ext)
About changing the appointment or parking or further discussion	Coordinator	F. Fedora	Phone (ext)
About long term effects	Sponsor (company)	Caps, Inc.	Phone
About issues you don't think you can discuss with the investigator	Institutional Review Board	IRC	1-800-472-3241 info@irb-irc.com

**E. FINANCIAL CONSIDERATIONS**

You are expected to pay the usual cost of a hatarectomy. This will not exceed \$500.00

Most insurers do not cover the cost of anything they consider experimental and occasionally deny coverage for an entire procedure. If cost is a consideration, you should discuss this further with the investigator.

You will be paid a total of \$100.00 for completing the study. It will be in 4 payments; \$25.00 for each day and \$25.00 bonus for completion.

*Subjects should have a clear idea of the magnitude of their financial responsibility. They should know if it will cost them more to participate, if they will be paid and if their insurance might be altered.*

You should also know that Caps. Inc. is paying Dr. Chapeau to purchase the haterizer if this study is successful before (90 days).

*The issue of conflict of interest is the subject of controversy.*

**F. ALTERNATIVES**

You can have a hatarectomy with the Haterizer which is the usual device.

*To make a choice one must have options. What are the choices and their relative risks and benefits*

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**H. RIGHTS**

Both subjects and investigators have some rights.

Subject rights:

- Participation should be voluntary. You should not feel compelled to agree.
- You should be told about the study and your questions should be answered to your satisfaction. You should have all the information you wish. Keep asking questions.
- If you refuse, there should be no penalty

- If you agree and wish to withdraw, you may. You should tell the investigator in case there is any safety issue.

In California, a Bill of Rights should be attached.

Investigator rights:

- It is the investigator’s right to accept or not accept participants. Occasionally studies must be stopped or individuals dropped from a study. Investigators can do this.

**PART 3 – GIVING CONSENT**

**THE SUBJECT**

If you agree to participate and if your questions have been answered, you should sign the form. You will be given a copy of this form to keep and to refer to as needed. You will also receive a copy of the California Experimental Subjects Bill of Rights.

_____	_____	_____
Signature	Printed name	Date

**THE PERSON EXPLAINING THE INFORMATION**

*IRC asks that the person discussing the issues with the participant take responsibility for co-signing.*  
I explained this information. I am co-signing this form to demonstrate joint responsibility in the effort to inform this person.

_____	_____	_____
Signature	Printed name	Date

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**ASSENT OF A MINOR -**

Although minors may not have the legal right to sign an agreement, they may have definite opinions. Minors who have the ability to read at about the 6<sup>th</sup> grade or more are being asked to read this form and to decide for themselves.

**PERMISSION OF A PARENT OR GUARDIAN**

As minors can't legally consent, the agreement of a custodial parent or guardian is also required in order to participate. If the minor has agreed and if you give your permission, he or she can be enrolled.

_____	_____	_____
Signature	Printed name	Date
_____		
Relationship to subject		

**PERMISSION / CONSENT OF LEGALLY AUTHORIZED GUARDIAN**

*This section should be included only if the IRB is being asked to allow proxy consent.*

If the potential subject is someone who cannot decide independently, that person cannot give complete consent. As the legally authorized person, you are being asked to give your permission. The person who is to be enrolled must be included in the discussion to the extent that it is possible and, if that person refuses, that refusal should normally be honored.

If you agree, you are giving your permission – on behalf of the subject – to enroll him or her into this study.

_____	_____	_____
Signature	Printed name	Date
_____		
Relationship to subject		

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**CALIFORNIA EXPERIMENTAL SUBJECT'S  
BILL OF RIGHTS**

The rights below are set out by the California legislature in 1978 as the rights of every person asked to be in a research study. This page should accompany a information/consent form giving information about the proposed study.

- As an "experimental" or "research" subject you have the following rights:
1. To be told what the study is trying to find out.
  2. To be told what will happen to you and whether any of the procedures, drugs, or devices is different from what would be used in standard practice.
  3. To be told about the frequent and/or important risks, side effects, or discomforts of the research drugs, devices, or procedures.
  4. To be told if you can expect any benefit from participating and, if so, what the benefit might be.
  5. To be told the other choices you have and how they compare to being in the study.
  6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study.
  7. To be told what sort of medical treatment is available if any complications arise.
  8. To refuse to participate at all or to change your mind about participation after the study is started. This decision will not affect your right to receive the care you would receive if you were not in the study.
  9. To receive a copy of the signed and dated consent form.
  10. To be free of pressure when considering whether you wish to agree to be in the study.

If you have questions you should ask the researcher or research assistant. You may contact Independent Review Consulting, which is concerned with protection of subjects. You may reach the IRC office during business hours.

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