
MEDICAL FACULTY ASSOCIATES

T H E G E O R G E W A S H I N G T O N U N I V E R S I T Y

Research Consent Form

Persistent Sexual Effects of Finasteride for Male Pattern Hair Loss

GW IRB Reference number: IRB # 021009

Principal Investigator: Michael Irwig MD Telephone number: (202)-741-2489

Sub Investigators: Swapna Kolukula MD, Aameeka Pannu

1) INTRODUCTION

You are invited to participate in a research study regarding the medication finasteride (Propecia). Your participation is entirely voluntary.

You do not have to take part in this study to receive care at George Washington University Medical Faculty Associates (MFA). The research may provide knowledge that may help patients and doctors to better understand the possible side effects associated with finasteride. This study is being conducted by the investigators listed above from the Department of Medicine.

2) WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see whether finasteride may be associated with persistent sexual side effects (low libido, erectile dysfunction, decreased orgasm, etc.) in younger men taking the medication for male pattern hair loss.

3) WHAT IS INVOLVED IN THIS STUDY?

If you choose to take part in this study, you will be asked to answer several questions regarding your use of finasteride, and your medical, psychiatric and social histories. Information will be solicited regarding current and past sexual function. Most of the questions will be conducted during a telephone interview lasting less than 30 minutes. A 5-item questionnaire will also be emailed for completion before the interview.

4) WHAT ARE THE RISKS OF PARTICIPATING IN THIS STUDY?

Potential risks are breach of confidentiality and emotional discomfort in answering questions regarding sexual function. You may skip any questions that you do not feel comfortable answering or request to stop the interview at any point. You may discontinue participation at any time without loss of medical care that you are currently receiving.

5) ARE THERE POTENTIAL BENEFITS TO TAKING PART IN THIS STUDY?

You may not directly benefit from the study, however, we hope that the study will provide important data that will be published describing the potential sexual side effects that develop in younger men taking finasteride for male pattern hair loss.

6) WHAT ARE MY OPTIONS?

You do not have to take part in this study if you do not want to participate. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. We feel that this study will not hinder you in any way.

7) WHAT WILL IT COST ME IF I DECIDE TO PARTICIPATE IN THIS STUDY?

Nothing.

8) WHAT ABOUT CONFIDENTIALITY?

Your information will be kept as confidential as possible. Access to study records will be limited to those who need the information for purposes of this study. All records are kept in a secure location and access is limited to research study personnel. Your name and other identifiable information (telephone number, email address, etc) will be kept on a separate key from the rest of the information such that your information will be anonymous for purposes of the data analysis. The results of this research study may be presented at scientific or medical meetings or published in scientific journals.

9) HOW WILL MY PRIVACY BE PROTECTED?

Federal law requires that hospitals, researchers and other healthcare providers (like physicians and labs) protect the privacy of health information that identifies you. You are free to not allow these uses and releases by not signing this form.

By signing this form, you allow the use, sharing, copying, and release of your protected health information in connection with this study by:

- the Study provider and the research team;
- GWU Institutional Review Board (“IRB”) or its authorized representatives, accrediting agencies, as well as representatives of the Office of Human Research Protections (OHRP) who may review your records to ensure that your rights as a research subject are protected;

Protected health information that may be used and released (disclosed) in this study includes information such as:

- This consent form;
- Demographic information: name, year of birth, sexual orientation, career;
- Information obtained from you to be used in the Study as a result of interview and questionnaire described at #3 above

This permission does not end unless you cancel it, even if you leave the study. You can cancel this permission any time except where a healthcare provider has already used or

