

Appendix 1. MsFLASH Vaginal Health Trial recruitment letter (2-sided)



Millions of women are bothered by postmenopausal vaginal symptoms, including dryness and pain with sex. Are you one of them?

After menopause, up to 50% of women have vaginal problems such as dryness, itching, irritation, burning, or pain with sexual activity. Despite the large number of women affected, very little is known about how standard treatments for vaginal symptoms compare or how they affect underlying biological causes of vaginal problems.

Researchers at Fred Hutchinson Cancer Research Center, the University of Minnesota, and Group Health Research Institute, are doing a study funded by the National Institute on Aging. The purpose of our study is to learn more about vaginal symptoms as women age and compare two popular treatments for symptom relief — a vaginal moisturizer and a low dose estrogen tablet that is placed in the vagina.

Our goal is to improve knowledge that will help to relieve vaginal symptoms, a much overlooked area of women's health.

We are seeking 300 women to help us with a 12-week study.

You may be eligible if:

- You are between the ages of 45 – 70.
- Your periods stopped more than 2 years ago.
- You have bothersome vaginal symptoms such as dryness, itching, burning, or pain.

See additional information on the back of this letter.

If you would like more information about this study, please visit our website at: fredhutch.org/MsFLASH

If you are interested in enrolling, please contact us at 1-800-270-5213 or contactmsflash.org. Leave your name and phone number and we will call you. There is no obligation to participate.

Thank you for your consideration.

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You can help us evaluate treatments to relieve women's symptoms and learn more about vaginal health as women age.





Here is some additional information about the study.

If you are eligible:

- You will be asked to come to 3 clinic visits over 12 weeks.
- You will be asked to fill out questionnaires and symptom diaries at home.
- You will be asked to use both vaginal tablets and vaginal gel for 12 weeks.
- Each clinic visit will involve a physical exam done by our study nurse or doctor, including a pelvic exam.
- To thank you for being in the study you would receive between \$150-300 if you finish all study activities.

If you have any of the following health conditions, you will not be eligible for the study:

- Current unexplained abnormal vaginal bleeding
- Pelvic or vaginal surgery in prior 60 days
- Current cancer treatment
- Current or past thromboembolic disease (pulmonary embolus or deep vein thrombosis, not including thrombophlebitis), heart attack, or stroke
- Current severe liver disease
- Current or past breast or endometrial cancer or pre-cancer

If you are taking the following medications, you will not be eligible for the study:

- Hormonal contraceptives
- Tamoxifen
- Evista
- Ospemifene



For more information about the MsFLASH studies, visit our website at

fredhutch.org/MsFLASH