

*Draft - INTRODUCTION LETTER*

Dear [*Participant's Name*]:

We are pleased to let you know that we have received funding from the National Institutes of Health to study diet and age-related eye disease. We are inviting you to take part in this program because you are enrolled in the Women's Health Initiative. There is no cost to you if you participate.

The purpose of this study is to find out whether certain aspects of **diet** are related to developing of two age-related eye diseases:

- **Cataract**, which affects the eyesight of the majority of older women over 75 years of age, and
- **Age-related macular degeneration**, which is the most common cause of blindness in older adults.

By comparing the diets of people who have and do not have cataract and/or macular degeneration, we can learn more about whether diet could delay or prevent these diseases, allowing women to enjoy better vision as they age without the need for medical intervention.

The Women's Health Initiative staff is conducting this study in collaboration with the faculty and staff of the University of Wisconsin Eye Department. This study is part of a larger study that also includes women in the Women's Health Initiative in Iowa and Oregon. We have enclosed a Fact Sheet to give you more details.

Please mail back the enclosed card to let us know if you are interested in participating. After we receive the card, we will call to schedule an appointment and answer any questions you may have about the study. You may also call the Women's Health Initiative with any additional questions (Toll-free at **(800) 944-9472** or locally at **(608) 827-1600**).

We thank you for the time you have taken to consider this study and for your support of scientific research to improve the health of women.

Sincerely,

Julie Mares-Perlman, PhD  
Principal Investigator

Catherine Allen, PhD  
Principal Investigator  
Women's Health Initiative

Barbara Blodi, MD  
Co-Investigator

Enclosures

*D R A F T*  
**Women's Health Initiative  
Diet and Eye Disease Study**

*Fact Sheet*

**WHAT DOES PARTICIPATION INVOLVE?**

1. You will make one trip to the University of Wisconsin Eye Clinic for eye tests to:
  - check your distance vision,
  - examine the retina or back of the eye with a test that measures the pigmentation, and
  - dilate your pupils with drops, take photographs of the lenses of both eyes to determine whether cataracts are present and the retina to determine whether signs of macular degeneration are present.
2. We will send you four questionnaires that will take about 60 minutes to complete. On these surveys we ask you to give us updated information on your:
  - diet and use of supplements,
  - use of sunglasses and hats, and
  - family history of cataract and macular degeneration.You may complete these questionnaires at home and bring them to your eye examination.

**WHEN AND WHERE WILL THE TESTING BE DONE?** The examinations will begin in August 2000 and will take place in the University of Wisconsin's **University Station Eye Clinic** (near the University of Wisconsin Hospital). You will be seen at your convenience. The tests take approximately 1½ to 2 hours to complete. You will be asked to bring your glasses or contact lenses to the examination.

**IS THERE A CHARGE FOR THE EXAMINATION?** No charge is made to you or your insurance carrier.

**IS THERE A BENEFIT?** A benefit of this study is that you will be made aware of whether there are serious problems with your eyes, such as cataract or macular degeneration, that require attention. This information will be sent to you and to any of your doctors that you choose. Address information for your doctor(s) will be obtained at the time of the examination. **However, this is not a complete eye examination and does not take the place of regular visits to your ophthalmologist and optometrist.**

**IS THERE ANY DISCOMFORT?** There should be no discomfort involved with the eye examination. Because your pupils will be dilated, you will not be able to read for a few hours after the tests.

**IS THERE ANY HAZARD?** There is a slight risk of mild local allergic reaction from drops used to dilate the pupil. These will not be given if there is a history of allergy to these medications. There is a very small risk that dilating the pupils might cause an attack of angle closure glaucoma. We will minimize this risk by examination of the front of your eyes before using the dilating drops, and we will not dilate your eyes if we feel that you are at risk. If acute angle closure glaucoma

were to result from dilation of the pupils, it is possible that medical or surgical management would be necessary.

*D R A F T*

**Response Card (side 1 of postcard):**

|   |   |
|---|---|
| Diet and Age-Related Eye Disease in the Women's Health Initiative |   |
| _____   | I am interested in being a part of this study.<br>Please call me to discuss my participation. |
| _____   | I am <b>not</b> interested in being a part of this study.                                     |
| Thank you, again, for taking time to consider this study .        |   |

**Response Card (side 2 of postcard):**

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Women's Health Study Participant Name:

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Address:

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Women's Health Initiative  
University of Wisconsin Medical School  
UW-Madison Clinical Center  
6602 University Avenue  
Middleton, WI 53562

**DRAFT**

## **PHONE SCRIPT**

**(For people who do not mail back the response card)**

This is \_\_\_\_\_ (*scheduler's name*). I am calling from the Women's Health Initiative Eye Study. We recently sent you a letter that explains this new study. This study will help us understand diet and eye health. Do you have any questions about this study?

May we ask the Eye Clinic to call you to schedule an appointment?

***If yes:***

Thank you for your time. If you have any questions, please call us at the Women's Health Initiative. We will send you a consent form and some questionnaires which you can bring with you on the day of the exam.

***If no:***

Thank you for your taking time to consider this study and for your support of studies on women's health. If you have further questions regarding these studies, please do not hesitate to call us at the Women's Health Initiative.

## **PHONE SCRIPT**

**(For people who mail back the response card and indicate interest in participating)**

This is \_\_\_\_\_ (*scheduler's name*). I am calling from the Women's Health Initiative Eye Study. We received your card indicating your interest in this study. Do you have any questions about this study?

May we schedule an appointment for eye testing? Before your appointment, I will mail you the study questionnaires and a consent form. Please bring them with you to the eye exam.

Thank you for your time and support of these studies to improve women's health. If you have any further questions, please call us at the Women's Health Initiative.