

## CONSENT FORM TEMPLATE

### DIET AND AGE-RELATED EYE DISEASE RESEARCH STUDY OF THE WOMEN'S HEALTH INITIATIVE

You are invited to take part in an ancillary study of the Women's Health Initiative, a program sponsored by the National Institutes of Health, at no cost to you. You may decline to participate or may withdraw from participation at any time without affecting your participation in the Women's Health Initiative and without affecting the type of medical or eye care that you will receive.

**PURPOSE:** The purpose of this research study is to investigate whether certain aspects of diet are related to the occurrence of two age-related eye diseases: cataract and macular degeneration. By comparing the diets of people who have and do not have these age-related eye diseases, we can learn more about whether diet could prevent them. Cataract affects the eyesight of the majority of older women over 75 years. Age-related macular degeneration is the most common cause of blindness in older adults. If we could prevent or delay these diseases, women could enjoy better vision into old age without the need for medical intervention.

**WHY HAVE YOU BEEN SELECTED?** You have been selected because you have previously participated in the Women's Health Initiative.

#### WHAT DOES PARTICIPATING INVOLVE?

1. You will make one trip to the \_\_\_\_\_ Clinic for the following eye tests:
  - 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 degenerationYou 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 \_\_\_\_\_ 2000 and will take place \_\_\_\_\_ Eye Clinic. You will be seen at your convenience. The tests take approximately 1½ to 2 hours to complete. You will be asked to bring any glasses or contact lenses that you wear 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 problems with your eyes 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. However, some people may find the photographs annoying. 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 attempt to further 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.

**WILL COMPENSATION BE MADE FOR ANY INJURY RESULTING FROM THIS RESEARCH EXAMINATION?** In the event that physical injury occurs as a result of this research, the University of Wisconsin does not automatically provide reimbursement for medical care or other compensation. If physical injury is suffered in the course of research, or for more information, please notify the investigator in charge. For information on the rights of research participants, please call the Patient Relation Services at the University of Wisconsin Hospital at (608) 263-8009.

**WHO WILL RECEIVE THE RESULTS OF THE EXAMINATION?** All of your study records will be kept confidential to the extent required by law. Your personal identity will not be revealed in any publication or release of results. If a health condition is detected during this examination, you will be told about it and the information will be given to your doctor or clinic. Only staff at the University of Wisconsin Ophthalmology and Visual Sciences Department and WHI staff at the University of Wisconsin Clinical Center in Madison, Wisconsin, and the Clinical Coordinating Center at the Fred Hutchinson Cancer Research Center in Seattle, Washington, will have access to your study number, name, social security number and address for the purpose of study-wide mailings, as well as maintaining and updating your study records. Study records will be kept indefinitely for analysis and follow-up.

**OTHER INFORMATION:** If you have any questions about any aspect of the study or your rights as a volunteer, you may call: WHI Clinical Center at the University of Wisconsin-Madison at (608) 263-3237. Before you sign this form, please ask any questions on any part of this study that is unclear to you.

**YOU MAY TAKE AS MUCH TIME AS YOU WISH TO THINK THIS OVER. BEFORE YOU SIGN THIS FORM, PLEASE ASK ANY QUESTIONS ON THE ASPECTS OF THIS STUDY WHICH ARE NOT CLEAR TO YOU. WE WILL ATTEMPT TO FULLY ANSWER ANY QUESTIONS YOU MAY HAVE PRIOR TO, DURING, OR FOLLOWING THE STUDY.**

**AUTHORIZATION:** I, \_\_\_\_\_, have read the above and choose to participate in the study project described. I agree to the release of medical information by study physicians to my physician(s) or other health care providers. I also agree to the release of medical information to study physicians from my physician(s) or from other health care providers. My signature also indicates that I have received a copy of this consent form.

Participant Signature

Date

Principal Investigator/Person Obtaining Consent

Date