Form 320 – Authorization to Use or Release Medical Record Information for Research

SELECT Eye Endpoints (SEE) Study (S0000B)
Form 320: Authorization to Use or Release Medical Record Information for Research

Participant ID	Ppt Initials (L, F, M)	Study Site #	Contact #

Medical records to be obtained by (check one) **Harvard Medical School** **Study Site**

Study Site: FAX completed form to 617-278-2030

My signature below indicates that I have read and understand this document and grant permission to William G. Christen, ScD, Associate Professor of Medicine, Brigham and Women's Hospital, Harvard Medical School, 900 Commonwealth Avenue East, Boston, MA 02215, to review a copy of my records for the eye condition(s) specified below:

Signature _____ Today's Date _____

Print Name _____

1. Since your last SELECT contact, were you diagnosed with (circle all that apply):

   Macular degeneration: left eye right eye Date of diagnosis: _____ month/year

   Cataract: left eye right eye Date of diagnosis: _____ month/year

2. Please provide date(s) of office visit(s): From _____ month/year to _____ month/year

3. Print the name and contact information for the Ophthalmologist/Optometrist who treated you:

   Doctor or Clinic: _____

   Street Address: _____

   City: _____ State: _____ Zip: _____

   Telephone: (_____) _____

4. If another Ophthalmologist/Optometrist also treated you, print that doctor's name and contact information:

   Doctor or Clinic: _____

   Street Address: _____

   City: _____ State: _____ Zip: _____

   Telephone: (_____) _____

COPY VALID AS ORIGINAL

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Principal Investigator: **William G. Christen, ScD**
Protocol Title: **SELECT Eye Endpoints (SEE) Study (S0000B)**

Federal law requires that we as researchers, health care providers, and physicians' networks protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health and conditions ("protected health information"). If you agree to the described uses within our group (Brigham and Women's Hospital and Harvard Medical School) and sharing of your protected health information with collaborators outside of our group, then after reading this entire document, please sign your name above. If you have questions, you can contact the researcher listed under Study Contacts at the end of this form.

1. Why will protected health information about me be used or shared with others?

To conduct and oversee the research being conducted in SELECT Eye Endpoints Study.

To ensure the research meets legal, institutional, and accreditation requirements. A copy of the Partners Notice for Use and Sharing of Protected Health Information, which provides more information about how Partners and its affiliates use and share protected health information, can be found on the following website: www.partners.org.

2. With whom may my protected health information be shared?

All reasonable efforts will be made to protect the confidentiality of your protected health information, including the use of unique study ID numbers instead of name. Protected health information may be shared with the following others for the reasons noted above:

The Brigham and Women's Hospital and Harvard Medical School and its affiliated researchers and entities participating in the research will use and share your protected health information. In addition, the Brigham and Women's review board that oversees the research and its affiliated staff who have a need to access this information to carry out their responsibilities (for example, oversight, quality improvement) will be able to use and share your protected health information.

Outside individuals or entities that have a need to access this information to perform functions on behalf of the Brigham and Women's Hospital and its affiliates (for example, collaborators reviewing and participating in research).

Other researchers and medical centers participating in this research, if applicable.

Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law.

A Data and Safety Monitoring Committee organized to oversee this research, if applicable.

We recognize that some of those who receive protected health information may not have to satisfy the privacy requirements that we do and may re-disclose it, so we share this information only if necessary and we use all reasonable efforts to request that those who receive it take steps to protect your privacy.

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3. What protected health information about me will be used or shared with others during this research?

Existing self-reported information from questionnaires and previously released medical records.

New health information created from study-related tests, procedures, visits, and/or questionnaires.

4. For how long will protected health information about me be used or shared with others?

There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed because research is an ongoing process, during which information may be analyzed and re-analyzed in light of scientific and medical advances, or reviewed for quality assurance, oversight, or other purposes.

5. Statement of privacy rights:

You have the right to withdraw your permission for the researchers and participating entities to use or share your protected health information. We will not be able to withdraw all of the information that already has been used or shared with others to carry out the research or any information that has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure the quality of the study. If you want to withdraw your permission, you must do so in writing by contacting the researcher listed as the Study Contact below.

You have the right to choose not to sign this form, which will prevent us obtaining and using information from your medical records related to the diagnosis you have reported. Choosing not to sign will not affect your present or future care at any healthcare facility and will not cause any penalty or loss of benefits to which you are otherwise entitled.

You have the right to request access to your protected health information that is used or shared during this research and that relates to your clinical treatment or billing status. To request this information, please contact the researcher listed under Study Contacts below.

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STUDY CONTACTS:

William G. Christen, ScD, Principal Investigator	Rosalyn Gray, BWH Human Research
(617) 278-0795 (call collect)	Compliance 1-800-633-6907 (toll-free)
HRC Protocol Number: **2003-P-001579**	(617) 724-5151 (call collect)

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Submission:	Fax completed form to the SELECT Eye Endpoints (SEE) Center at Harvard Medical School at 617-278-2030. **Do NOT** submit to the SELECT Statistical Center.
Completed by:	Participant
When to complete and submit:	Completed when a SEE participant reports a diagnosis of cataract and/or macular degeneration
Contact Number:	Contact number of the SELECT visit at which the participant reported the eye event of interest
Number of Pages:	3 pages. Page 1 is photocopied for the participant, faxed to Harvard, and retained by the site. The photocopy of page 1 and the originals of pages 2 and 3 are retained by the participant.

Form Instructions:

The purpose of this form is for the participant to grant permission for the SELECT Eye Endpoints (SEE) investigators to review relevant medical records from the treating eye doctor(s).

1. Fill in the key fields before giving the form to the participant for completion.
2. Check the box to indicate whether the SELECT Eye Endpoints (SEE) Center or the Study Site will obtain the medical records from the treating eye doctor(s).
3. Provide the participant with a photocopy of page 1 and the originals of pages 2 and 3.
4. FAX page 1 of the completed form to the SELECT Eye Endpoints (SEE) Center at Harvard Medical School at 617-278-2030.
5. Retain the original of page 1 and place in the participant's chart.

Participant signature, date and printed name:
These items are required. Check the printed name for legibility. The SELECT Eye Endpoints (SEE) Center will return any unsigned or undated forms to the Study Site for correction and resubmission.

1. **Information on eye diagnosis:**
   The participant should circle all of the categories that apply. If the participant is unsure whether a category applies, instruct him to circle it. The participant should record an approximate date of diagnosis for cataract and/or macular degeneration. If he is uncertain of the month or year of diagnosis, instruct him to record his best guess.

2. **Date(s) of office visit(s):**
   The participant should enter the approximate dates of treatment for the diagnosed eye condition. If he is uncertain of the month or year, instruct him to record his best guess.

3. **Name and contact information for primary treating eye doctor:**
   This is the most important question on the form. Assist the participant in completing all items as completely and legibly as possible. If the participant cannot recall some of the information, provide him with a pre-addressed mailing envelope for completing the form at home and mailing it to the Study Site.

4. **Name and contact information for secondary treating eye doctor:**
   If a second eye doctor treated the participant, assist the participant in completing all items as completely and legibly as possible. If the participant cannot recall some of the information, provide him with a pre-addressed mailing envelope for completing the form at home and mailing it to the Study Site.