I. General Information

NOTE: To be completed by the clinic coordinator by directly questioning the patient. Sentences within quotes should be read verbatim to the patient.

1. Birth date: __ __ - __ __ - 19__ __ (Month - Day - Year)

2. Age as of **last** birthday: __ __

3. Is patient age 50 or older?
   ( )$_1$ Yes ( )$_0$ No → **STOP:** This patient is ineligible

4. Sex: ( )$_m$ Male ( )$_f$ Female

5. "With which of the following racial or ethnic groups do you most closely identify?" (check one):

   White, not of Hispanic origin ( )$_1$
   American Indian or Alaskan Native ( )$_2$
   Asian or Pacific Islander ( )$_3$
   Black, not of Hispanic origin ( )$_4$
   Hispanic origin ( )$_5$
   Unable to answer ( )$_6$

6. "What is your current occupational status?" (check best answer):

   Employed with income ( )$_1$
   Housespouse ( )$_2$
   Retired ( )$_3$
   Unable to work ( )$_4$
   Student ( )$_5$
   Unemployed ( )$_6$

7. "Have you <u>ever</u> taken any of the following drugs at these dose levels?"

a. Mellaril or thioridazine hydrochloride at a dose $\geq$ 500mg daily? Yes ( )$_1$ No ( )$_0$

b. Thorazine or chlorpromazine hydrochloride at a dose of $\geq$ 1000mg daily? Yes ( )$_1$ No ( )$_0$

c. Aralen or chloroquine with a total lifetime dose of $\geq$ 100g? Yes ( )$_1$ No ( )$_0$

STOP: This patient is ineligible

8. "Do you **CURRENTLY** take any of the following medications?"

	Yes	No
a. Systemic steroids?	( )$_1$	( )$_0$
b. Mellaril or thioridazine hydrochloride?	( )$_1$	( )$_0$
c. Aralen or chloroquine?	( )$_1$	( )$_0$
d. Phenothiazide derivatives?	( )$_1$	( )$_0$

STOP: This patient is ineligible

9. "How would you describe your use of aspirin?" **(check only one)**

Never	( )$_0$
Occasionally	( )$_1$
Regularly	( )$_2$

9.A. How much aspirin does the patient take?

Less than 1 tablet per day	( )$_1$
One tablet per day	( )$_2$
More than one per day	( )$_3$

10. "Do you currently take daily multivitamins or vitamin supplements?"

( )1 Yes ( )0 No ( )2 Don't know → 10.A.

10.A. Check as many as apply. Do not include herbal supplements:

Vitamin	Yes
a. Multivitamin	( )1
b. Vitamin A	( )1
c. Vitamin B	( )1
d. Vitamin C	( )1
e. Vitamin E	( )1
f. Other, specify :	( )1

g. ______________________

____

11. "Do you currently take a daily zinc supplement other than what's contained in a multivitamin?"

( )1 Yes ( )0 No ( )2 Don't know

12. "Are you currently taking medication for hypertension?"

( )1 Yes ( )0 No

13. "Do you have diabetes?"

( )0 No ( )1 Yes ( )2 Don't know

14. "Have you ever smoked cigarettes on a daily basis?"

( )1 Yes → 14.A. ( )0 No

14.A. "How many years did you smoke cigarettes on a daily basis?" __ __

14.B. "Do you currently smoke cigarettes?"

Yes	( )1
No, quit less than one year ago	( )2
No, quit more than one year ago	( )3

15. "Are you currently participating in another randomized clinical trial of any condition, ocular or nonocular?"

( )1 Yes → 15.A. ( )0 No

15.A. Specify name of clinical trial:

____

____

You must have Coordinating Center approval before randomizing

Visit: 00	ID. No.: __ __ - __ __ __ - C
Form: IV	Name Code: __ __ __ __ __

16. Please record the patient's sitting blood pressure measurements:

    a. Systolic __ __ __ mm Hg

    b. Diastolic __ __ __ mm Hg

Do not read the following items 17 a – c aloud to the patient. Please complete these items using your own judgment.

17. Does the patient have any condition that:

    a. Makes 5-year survival unlikely

    ( )$_1$ Yes → **STOP** ( )$_0$ No

    b. Limits activity to the extent that return visits to the clinic are unlikely

    ( )$_1$ Yes → **STOP** ( )$_0$ No

    c. Precludes informed consent

    ( )$_1$ Yes → **STOP** ( )$_0$ No

STOP: This patient is ineligible

18. Print name and certification number of person who completed this section:

    ________________________ / __ __ __ __
    Name / Cert#

19. Date General Information was completed:

    __ __ - __ __ - __ __
    Month Day Year

Visit: 00 Form: IV	ID. No.: __ __ - __ __ __ - C Name Code: __ __ __ __ __

II. Visual Acuity Examination

NOTE: Both eyes of the patient must be tested. Circle each correct letter and put an x on each incorrect letter. Leave letters not attempted unmarked.

1. Correction obtained by subjective refraction (If Plano, enter zeros):

   a. Right Eye:

   + / – __ . __ __ + __ . __ __ X __ __ __
   Circle Sign Sphere Cylinder Axis

   b. Left Eye:

   + / – __ . __ __ + __ . __ __ X __ __ __
   Circle Sign Sphere Cylinder Axis

2. Does **EITHER EYE** have a myopic correction greater than eight diopters spherical equivalent?

   ( )$_1$ Yes ( )$_0$ No

STOP: This patient is ineligible

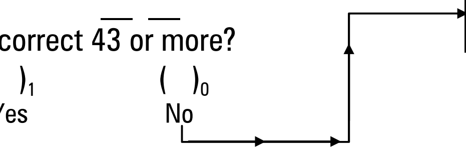
3. Letters read correctly at 3.2-meter distance:

RIGHT EYE - CHART 1

Acuity Equivalent	Chart 1 Letters	Number Correct
a. 20/250	N C K Z O	______
b. 20/200	R H S D K	______
c. 20/160	D O V H R	______
d. 20/125	C Z R H S	______
e. 20/100	O N H R C	______
f. 20/80	D K S N V	______
g. 20/64	Z S O K N	______
h. 20/50	C K D N R	______
i. 20/40	S R Z K D	______
j. 20/32	H Z O V C	______
k. 20/25	N V D O K	______
l. 20/20	V H C N O	______
m. 20/16	S V H C Z	______
n. 20/12	O Z D V K	______
o. Total number correct		__ __

p. Is (3.o.) total number correct 43 or more?

( )$_1$ Yes ( )$_0$ No



STOP: This patient is ineligible

Visit: 00	ID. No.: __ __ - __ __ __ - C
Form: IV	Name Code: __ __ __ __ __

4. Letters read correctly at 3.2-meter distance:

LEFT EYE - CHART 2

Acuity Equivalent	Chart 1 Letters	Number Correct
a. 20/250	D S R K N	______
b. 20/200	C K Z O H	______
c. 20/160	O N R K D	______
d. 20/125	K Z V D C	______
e. 20/100	V S H Z O	______
f. 20/80	H D K C R	______
g. 20/64	C S R H N	______
h. 20/50	S V Z D K	______
i. 20/40	N C V O Z	______
j. 20/32	R H S D V	______
k. 20/25	S N R O H	______
l. 20/20	O D H K R	______
m. 20/16	Z K C S N	______
n. 20/12	C R H D V	______
o. Total number correct		__ __

p. Is (4.o.) total number correct 43 or more?

( )1 Yes ( )0 No → **STOP:** This patient is ineligible

5. Print name and certification number of examiner:

______________________________ / __ __ __ __
Name Cert#

6. Date of visual acuity testing:

__ __ - __ __ - __ __
Month Day Year

Visit: 00 Form: IV	ID. No.: __ __ - __ __ __ - C Name Code: __ __ __ __ __

III. Contrast Sensitivity Testing

NOTE: Both eyes of the patient must be tested at 1 meter. Add +.5 diopters to patient's refractive correction at 3.2 meters. Circle each correct letter and put an X on each incorrect letter. Leave letters not attempted unmarked.

RIGHT EYE - Chart 4L

				Number Correct					Number Correct
1a.	V	R	S	____	2a.	K	D	R	____
1b.	N	H	C	____	2b.	S	O	K	____
1c.	S	C	N	____	2c.	O	Z	V	____
1d.	C	N	H	____	2d.	Z	O	K	____
1e.	N	O	D	____	2e.	V	H	R	____
1f.	C	D	N	____	2f.	Z	S	V	____
1g.	K	C	H	____	2g.	O	D	K	____
1h.	R	S	Z	____	2h.	H	V	R	____

LEFT EYE - Chart 2L

				Number Correct					Number Correct
3a.	H	S	Z	____	4a.	D	S	N	____
3b.	C	K	R	____	4b.	Z	V	R	____
3c.	N	D	C	____	4c.	O	S	K	____
3d.	O	Z	K	____	4d.	V	H	Z	____
3e.	N	H	O	____	4e.	N	R	D	____
3f.	V	R	C	____	4f.	O	V	H	____
3g.	C	D	S	____	4g.	N	D	C	____
3h.	K	V	Z	____	4h.	O	H	R	____

5. Print name and certification number of examiner:

   ______________________ / __ __ __ __
   Name Cert#

6. Date of contrast testing:

   __ __ - __ __ - __ __
   Month Day Year

Visit: 00 Form: IV	ID. No.: __ __ - __ __ __ - C Name Code: __ __ __ __ __

IV. Reading Test

NOTE: Both eyes of the patient must be tested at 40cm. Add +2.00 diopters to patient's refractive correction at 3.2 meters. Put an X on each incorrect word. Record time to nearest tenth of a second and the number of errors. Check all boxes for sentences not attempted. If a technical error (e.g. stopwatch malfunction) occurs during a sentence, code time as XX.X and errors as XX. Maximum time allowed is 99.9 seconds per sentence. Patient must attempt to read sentence for a minimum of 30 seconds before you end the test.

RIGHT EYE -- Chart 1

	Sentence	Not Attempted	Time	Errors
1R.	My father takes me to school every day in his big green car.	☐	__ __ . __	__ __
2R.	Everyone wanted to go outside when the rain finally stopped.	☐	__ __ . __	__ __
3R.	They were not able to finish playing the game before dinner.	☐	__ __ . __	__ __
4R.	My father asked me to help the two men carry the box inside.	☐	__ __ . __	__ __
5R.	Three of my friends had never been to a circus before today.	☐	__ __ . __	__ __
6R.	My grandfather has a large garden with fruit and vegetables.	☐	__ __ . __	__ __
7R.	He told a long story about ducks before his son went to bed.	☐	__ __ . __	__ __
8R.	My mother loves to hear the young girls sing in the morning.	☐	__ __ . __	__ __
9R.	The young boy held his hand high to ask questions in school.	☐	__ __ . __	__ __
10R.	My brother wanted a glass of milk with his cake after lunch.	☐	__ __ . __	__ __
11R.	I do not understand why we must leave so early for the play.	☐	__ __ . __	__ __
12R.	It is more than four hundred miles from my home to the city.	☐	__ __ . __	__ __
13R.	Our father wants us to wash the clothes before he gets back.	☐	__ __ . __	__ __
14R.	They would love to see you during your visit here this week.	☐	__ __ . __	__ __
15R.	The teacher showed the children how to draw pretty pictures.	☐	__ __ . __	__ __
16R.	Nothing could ever be better than a hot fire to warm you up.	☐	__ __ . __	__ __
17R.	The old man caught a fish here when he went out in his boat.	☐	__ __ . __	__ __
18R.	Our mother tells us that we should wear heavy coats outside.	☐	__ __ . __	__ __
19R.	One of my brothers went with his friend to climb a mountain.	☐	__ __ . __	__ __

Visit: 00	ID. No.: __ __ - __ __ __ - C
Form: IV	Name Code: __ __ __ __ __

LEFT EYE -- Chart 2

	Sentence	Not Attempted	Time	Errors
1L.	The three elephants in the circus walked around very slowly.	☐	__ __ . __	__ __
2L.	We could not guess what was inside the big box on the table.	☐	__ __ . __	__ __
3L.	The two friends did not know what time the play would start.	☐	__ __ . __	__ __
4L.	She wanted to show us the new toys she got for her birthday.	☐	__ __ . __	__ __
5L.	The mother told her son that she wanted him to go to school.	☐	__ __ . __	__ __
6L.	An old man took a picture of my sister and her little puppy.	☐	__ __ . __	__ __
7L.	Ten different kinds of flowers grow by the side of the road.	☐	__ __ . __	__ __
8L.	Put your first name on this paper if you will help tomorrow.	☐	__ __ . __	__ __
9L.	The father gave his children some fruit for lunch every day.	☐	__ __ . __	__ __
10L.	Please do not make noise while they are reading their books.	☐	__ __ . __	__ __
11L.	We sometimes take long walks together if it is warm outside.	☐	__ __ . __	__ __
12L.	The snow fell softly this morning before our family woke up.	☐	__ __ . __	__ __
13L.	Many people came to help us clean the place after the party.	☐	__ __ . __	__ __
14L.	He could see a bird outside if he looked through his window.	☐	__ __ . __	__ __
15L.	The teacher wanted the children to learn how to draw a boat.	☐	__ __ . __	__ __
16L.	We like to listen to music when we are eating our breakfast.	☐	__ __ . __	__ __
17L.	Three of my closest friends are going to visit him tomorrow.	☐	__ __ . __	__ __
18L.	She gave a glass of water to her mother before going to bed.	☐	__ __ . __	__ __
19L.	My brother was not feeling very well so he did not go today.	☐	__ __ . __	__ __

20. Print name and certification number of examiner:

______________________ / __ __ __ __
Name Cert#

21. Date of reading testing:

__ __ - __ __ - __ __
Month Day Year

Visit: 00	ID. No.: __ __ - __ __ __ - C
Form: IV	Name Code: __ __ __ __ __

V. Ophthalmological Review

1. Does **EACH EYE** have 10 or more large drusen (>125 microns) within 3000 microns of the foveal center?

   ( )1 Yes   ( )0 No → (go to 2)

2. Does **EITHER EYE** have geographic atrophy greater than 1 MPS disc area within 3000 microns of the foveal center or is there geographic atrophy within 500 microns of the foveal center?

   ( )1 Yes   ( )0 No

3. Does the patient have signs of diabetic retinopathy more severe than 10 red dots (microaneurysms or blot hemorrhages) within 3000 microns of the foveal center **or** macular edema in **EITHER EYE**?

   ( )1 Yes   ( )0 No

4. Does **EITHER EYE** have retinal changes related to high myopia?

   ( )1 Yes   ( )0 No

5. Does the patient have glaucoma that is likely to interfere with central vision during the next 5 years?

   ( )1 Yes   ( )0 No

STOP: This patient is ineligible

6. Is the patient currently taking any of the following macular toxic glaucoma drugs?

	Yes	No
a. Xalatan or latanoprost?	( )1	( )0
b. Propine or dipivefrin?	( )1	( )0
c. Epinephrine?	( )1	( )0

STOP: This patient is ineligible

Visit: 00	ID. No.: __ __ - __ __ __ - C
Form: IV	Name Code: __ __ __ __ __

7. Is **EITHER EYE** aphakic or pseudophakic?
   ( )1 Yes → go to 7A ( )0 No

   7A. Has it been at least three months since removal of the lens or lens implantation?
   ( )1 Yes ( )0 No → **STOP: This patient is ineligible**

   7B. Has it been at least 3 days since the capsulotomy?
   ( )1 Yes ( )0 No → **STOP: This patient is ineligible** ( )2 No Capsulotomy

8. Does **EITHER EYE** have lens opacity or other media opacity that will preclude good fundus photography or fluorescein angiography now or in the future?
   ( )1 Yes → **STOP: This patient is ineligible** ( )0 No

Please answer items 9 through 12 AFTER review of the fluorescein angiogram

9. Does **EITHER EYE** have evidence of neovascular AMD (CNV, disciform scar, or laser scar)?
   ( )1 Yes → **STOP: This patient is ineligible** ( )0 No

10. Does **EITHER EYE** have a serous pigment epithelial detachment?
   ( )1 Yes → **STOP: This patient is ineligible** ( )0 No

11. Has **EITHER EYE** ever had laser photocoagulation treatment to the retina?
   ( )1 Yes → **STOP: This patient is ineligible** ( )0 No

12. Does the patient have any <u>other</u> ocular disease unrelated to AMD?
   ( )1 Yes → go to 12A ( )0 No

   12A. Is this condition likely to impair visual acuity in the next 5 years?
   ( )0 No → **Pre-Randomization approval required by Reading Center**
   ( )1 Yes → **STOP: This patient is ineligible**

13. Print name and certification number of ophthalmologist:

   ______________________________ / __ __ __ __
   Name Cert#

14. Date of ophthalmologic review:

   __ __ - __ __ - __ __
   Month Day Year

Visit: 00	ID. No.: __ __ - __ __ __ - C
Form: IV	Name Code: __ __ __ __ __

VI. Photographs

NOTE: Stereo color photographs and the fluorescein angiogram of both eyes must be taken within 28 days prior to randomization.

1. Have the following required stereo color photographs been taken:

   a. Right eye macula? ( )$_1$ Yes ( )$_0$ No →

   b. Right eye disc? ( )$_1$ Yes ( )$_0$ No →

   c. Left eye macula? ( )$_1$ Yes ( )$_0$ No →

   d. Left eye disc? ( )$_1$ Yes ( )$_0$ No →

   → **STOP:** This patient is ineligible

2. Date the stereo color photographs were taken:

   __ __ - __ __ - __ __
   Month Day Year

3. Print name and certification number of photographer taking the stereo color photographs:

   ______________________ / __ __ __ __
   Name Cert#

4. Has the required fluorescein angiogram been taken?

   ( )$_1$ Yes ( )$_0$ No → **STOP:** This patient is ineligible

5. Date the fluorescein angiogram was taken:

   __ __ - __ __ - __ __
   Month Day Year

6. Print name and certification number of photographer performing the fluorescein angiography:

   ______________________ / __ __ __ __
   Name Cert#

Visit: 00 Form: IV	ID. No.: __ __ - __ __ __ - C Name Code: __ __ __ __ __

VII. Request for Randomized Assignment

*Note: If this patient is eligible the Clinic Coordinator should; **a)** ensure patient signed consent form, **b)** complete the eligibility checklist, **c)** fax the eligibility checklist to the Coordinating Center, **d)** confirm receipt by calling the Coordinating Center, and **e)** arrange logistics of randomization.*

1. Date patient signed consent form:

   __ __ - __ __ - __ __
   Month Day Year

2. Has the eligibility checklist been completed?

   ( )1 Yes ( )0 No → Complete Eligibility Checklist

3. Patient location code: →

   __ __ - __
   Clinic Site

4. Date treatment assignment allocated:

   __ __ - __ __ - __ __
   Month Day Year

5. Eye assigned to laser treatment:

   ( )0 Right ( )1 Left

6. Date laser treatment performed: → Complete Initial Laser Treatment Form

   __ __ - __ __ - __ __
   Month Day Year

Visit: 00	ID. No.: __ __ - __ __ __ - C
Form: IV	Name Code: __ __ __ __ __

VIII. Administrative Matters

1. Date patient is scheduled to return for Safety Check 03 (three months after randomization):

   __ __ - __ __ - __ __
   Month Day Year

2. Print name and certification number of clinic coordinator who checked this form for completeness:

   ______________________ / __ __ __ __
   Name Cert#

3. Date checked for completeness:

   __ __ - __ __ - __ __
   Month Day Year

INSTRUCTIONS FOR CLINIC COORDINATOR

SEND ORIGINALS TO COORDINATING CENTER

- Coord Center Transmittal Log ❑
- Initial Visit Form ❑
- Treatment Form ❑
- Quality of Life Assessment ❑

SEND ORIGINALS TO READING CENTER

(Send All Materials Together)

- Photographic Materials Transmittal Log ❑
- Color Photographs ❑
- Fluorescein Angiograms ❑
- Treatment Color Photographs ❑
- Photograph Inventory Form ❑
- Treatment Photograph Inventory Form ❑

KEEP IN YOUR CLINIC FILES

Originals:

- Patient Information ❑
- Eligibility Checklist ❑
- Patient Consent Form ❑

Copies or Duplicates:

- All Data Forms ❑
- All Transmittal Logs ❑
- All Photograph Inventory Forms ❑
- All Photographs ❑
- All Fluoresceins ❑

Visit: 00	ID. No.: __ __ - __ __ __ - C
Form: IV	Name Code: __ __ __ __ __