

OHTS Qualifying Assessment: QA

| |
|------------------------------|
| Coordinating Center use only |
| Rec'd..... |
| Log'd |
| Chk'd |
| Entr'd |

Patient ID: 9

Date: / / 19

mm dd yy

- Print in black ink
- **Complete questions 1 through 14 for all patients who begin the QA process**
- Complete patient ID on each page
- As many as 3 visits may be required to complete the qualifying assessment
- Send original to CC for eligible and ineligible patients upon completion of QA
- Keep a photocopy of the completed QA for your clinic
- If patient appears eligible after QA, schedule randomization visit in 4 - 6 weeks

Checklist

- | | | Form Page |
|-------------------------------------|---|-----------|
| <input checked="" type="checkbox"/> | Check when completed | |
| <input type="checkbox"/> | Patient Background Information | 2 |
| <input type="checkbox"/> | Ocular History..... | 3 |
| <input type="checkbox"/> | Medical History..... | 4 |
| <input type="checkbox"/> | Refraction & Best-Corrected Snellen and ETDRS Visual Acuity..... | 5 |
| <input type="checkbox"/> | First IOP Determination..... | 6 |
| | Minimum washout: • 1 wk. - Miotics | |
| | • 2 wks. - Alpha 2 Agonists | |
| | • 4 wks. - B-Blockers - Epinephrine/Dipivefrin | |
| <input type="checkbox"/> | Second IOP Determination | 6 |
| | 2nd IOP can be done 2 hrs. after 1st IOP, but a separate visit is recommended | |
| <input type="checkbox"/> | Slit-Lamp Examination | 7 |
| | Humphrey Visual Field Series | 8 |
| | Use an OHTS certified perimeter only | |
| <input type="checkbox"/> | a. Field #1 - may use a prestudy field if done within 12 wks. of 1st QA visit (#49) | |
| <input type="checkbox"/> | b. Field #2 (#50) | |
| <input type="checkbox"/> | c. Field #3 (if necessary) - two fields may be performed on the same day if spaced at least 1 hour apart (#51) | |
| <input type="checkbox"/> | Stereo Optic Disc Photography | 8 |
| | may use prestudy photos if done within 12 wks. of 1st QA visit | |
| <input type="checkbox"/> | If the qualifying assessment is stopped at any time before completion (e.g., the patient is ineligible), please check the box and give a brief explanation: | 25 |
| | | |
| | | |
| | | |
| <input type="checkbox"/> | Date Informed Consent is signed..... | 26 |
| | <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> mm dd yy | 26 |
| <input type="checkbox"/> | Date Decline to Participate is signed..... | 32 |
| | <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> mm dd yy | 32 |

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Patient Background Information

(Complete this page for all patients who begin QA.)

1. **Gender** 25
1 Male
2 Female
2. **Race** 25
Ask patient, "Do you consider yourself (read list)..."
1 American Indian or Alaskan Native
2 Asian or Pacific Islander
3 Black, not of Hispanic origin
4 Hispanic
5 White, not of Hispanic origin
6 Other: _____
3. **What is the highest level of education you've completed?** 27
1 Grade 6 or less
2 Grade 7-11
3 Grade 12 (high school graduate or GED)
4 One or more years of college
5 One or more years of graduate education
4. **What is your marital status?** 27
1 Single, never married
2 Married
3 Divorced/Separated
4 Widowed
5. **How old are you?** 29
6. **What is your date of birth?** / /
7. **Is patient's age between 40 and 80 inclusively?** 38
1 No (Patient is ineligible)
2 Yes
8. **Do you anticipate moving out of this area permanently in the next 5 years?** 39
1 Yes (If yes, consider excluding the patient)
2 No

History taken by 40

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Ocular History

(Complete this page for all patients who begin QA.)

9. **Have you ever had any of the following eye surgeries?**

- Penetrating keratoplasty
- Retinal detachment repair
- Glaucoma surgery including laser trabeculoplasty, laser iridotomy, combined cataract/filtering surgery
- Aphakic cataract extraction or A/C IOL cataract extraction

1 Yes (Patient is ineligible) 25

2 No

10. **Have you used any eyedrops during the last 3 months, including over-the-counter medicines, artificial tears, or medication for pinkeye or allergies?**

1 Yes 26

2 No

11. **Investigator/Coordinator: Does patient use ophthalmic steroids? See MOP Ch. 12 for list of ophthalmic steroids:**

1 Yes (Patient is ineligible) 27

2 No

12. **Have you ever used eyedrops to lower the pressure in your eyes?**

1 Yes 28

2 No

13. **Investigator/Coordinator: Lens status of patient**

| | |
|--|--|
| <p><u>OD</u></p> <p><input type="checkbox"/>1 Aphakic</p> <p><input type="checkbox"/>2 Phakic</p> <p><input type="checkbox"/>3 Pseudophakic - PC lens</p> <p><input type="checkbox"/>4 Pseudophakic - AC lens</p> | <p><u>OS</u></p> <p><input type="checkbox"/>1 Aphakic</p> <p><input type="checkbox"/>2 Phakic</p> <p><input type="checkbox"/>3 Pseudophakic - PC lens</p> <p><input type="checkbox"/>4 Pseudophakic - AC lens</p> |
|--|--|

31

History taken by

OHTS Qualifying Assessment: QA

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mm dd yy

Medical History

(Complete questions 14a - 14i for all patients who begin QA.)

| 14. Has a doctor ever told you that you have any of the following conditions? | Yes (1) | No (2) | Unknown (9) | |
|--|--|--------------------------|----------------------------|--------|
| a. High Blood Pressure (hypertension) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 25 |
| b. Low Blood Pressure (hypotension) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 26 |
| c. Diabetes, or sugar in the blood | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 27 |
| d. Asthma | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 28 |
| e. Chronic Lung Disease (emphysema, chronic bronchitis, etc.) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 29 |
| f. Stroke | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 30 |
| g. Cancer | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 31 |
| h. Heart Disease | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 32 |
| i. Other conditions _____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 33 |
| 15. If patient is female, ask "Is it possible that you are or could become pregnant?" | <input type="checkbox"/> * | <input type="checkbox"/> | <input type="checkbox"/> * | 34 |
| 16. Result of Pregnancy Test- <input type="checkbox"/> 1 Positive (Patient is ineligible) <input type="checkbox"/> 2 Negative | *If yes, or unknown, request a HCG urine test and record. | | | 35 |
| 17. Do you regularly take systemic steroid medication, such as prednisone? <input type="checkbox"/> 1 Yes (Patient is ineligible) <input type="checkbox"/> 2 No | | | | 36 |

Investigator: Answer questions 18 and 19 before proceeding further.

| | | |
|--|--|----|
| 18. Does this patient have any condition(s) that can cause visual field loss (pituitary lesion, pseudotumor, demyelinating disease, etc.)? <input type="checkbox"/> 1 Yes (Patient is ineligible) <input type="checkbox"/> 2 No | 19. Does this patient have any health condition(s) that would prevent completion of 5 years of follow-up in the study? <input type="checkbox"/> 1 Yes (Patient is ineligible) <input type="checkbox"/> 2 No | 37 |
|--|--|----|

➤ **If patient appears eligible, complete consent procedure before continuing with refraction and acuity**

History taken by 39
 END03

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mm dd yy

Refraction

20. **Refraction OD** 1 plus 1 plus 2 minus 2 minus x 25
21. **Refraction OS** 1 plus 1 plus 2 minus 2 minus x 38
- Refraction taken by 51

Snellen best-corrected visual acuity

22. **Snellen visual acuity** OD / 54
23. **Snellen visual acuity** OS / 59
24. **Is Snellen visual acuity worse than 20/40 in either eye?**
1 Yes (Patient is ineligible) 64
2 No

Snellen acuity taken by 65

ETDRS best-corrected visual acuity

ETDRS visual acuity - OD

25. Testing distance in meters: 1 4m 2 3.2m 3 2.5m 4 2.0m 68
26. Total number correct: OD 69

ETDRS visual acuity - OS

27. Testing distance in meters: 1 4m 2 3.2m 3 2.5m 4 2.0m 71
28. Total number correct: OS 72

ETDRS acuity taken by

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- **Minimum washout**
 - 1 Wk. - Miotics
 - 2 Wks. - Alpha 2 Agonists
 - 4 Wks. - Beta-Blockers
 - Epinephrine/Dipivefrin
- **IOP is measured by an Operator and a Recorder**
- **Two IOP Determinations are required**
 - Each determination is the mean of 2 IOPs or the median of 3 IOPs
 - The 3rd IOP is required if the first two IOPs are greater than 2 mm Hg apart

Patient ID: 9

| 1st IOP Determination | 2nd IOP Determination |
|---|---|
| 29. Exam Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | 35. Exam Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| mm dd yy | mm dd yy |
| 30. Time <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> 1 am <input type="checkbox"/> 2 pm | 36. Time <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> 1 am <input type="checkbox"/> 2 pm |
| OD OS | OD OS |
| 31. 1st IOP <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mm Hg | 37. 1st IOP <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mm Hg |
| 32. 2nd IOP <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mm Hg | 38. 2nd IOP <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mm Hg |

➤ **Are the 1st and 2nd IOP determinations less than or equal to 2 mm Hg apart?** ◀

Yes: Enter their average on line 34. **Yes:** Enter their average on line 40.

No: Take a 3rd IOP and enter on line 33. **No:** Take a 3rd IOP and enter on line 39.

| | |
|--|--|
| 33. 3rd IOP <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mm Hg | 39. 3rd IOP <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mm Hg |
|--|--|

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➤ **If a 3rd IOP is taken, enter the median (middle value) of the 1st, 2nd, and 3rd IOP** ◀

| | |
|--|--|
| <p>On line 34:</p> <p>34. 1st IOP Determination <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> Do not round</p> <p>Operator - IOP cert. <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Recorder - IOP cert. <input type="text"/> <input type="text"/> <input type="text"/></p> | <p>On line 40:</p> <p>40. 2nd IOP Determination <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> Do not round</p> <p>Operator - IOP cert. <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Recorder - IOP cert. <input type="text"/> <input type="text"/> <input type="text"/></p> |
|--|--|

41. **Qualifying IOPs: Enter average of 1st and 2nd Determination for each eye:**

Round to the nearest whole number: **OD** mm Hg **OS** mm Hg

42. Is Qualifying IOP (line 41) less than or equal to 32 mm Hg in both eyes? 1 Yes 2 No

43. Is Qualifying IOP (line 41) greater than or equal to 21 mm Hg in both eyes? 1 Yes 2 No

44. Is Qualifying IOP (line 41) greater than or equal to 24 mm Hg in at least one eye? 1 Yes 2 No

(If "no" to #42 or #43 or #44, patient is ineligible)

57
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1
9
25
37
43
49
53
54
55
END06

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mm dd yy

Slit-Lamp & Dilated Fundus Examination

45. **Does patient have evidence of any of the following exclusion criteria?**
- a. Pigmentary glaucoma 1 Yes 2 No 25
 - b. Pseudoexfoliation 1 Yes 2 No 26
 - c. Uveitis 1 Yes 2 No 27
 - d. Diabetic retinopathy
(i.e. microaneurysm or retinal hemorrhage) 1 Yes 2 No 28
 - e. Narrow angles
(Is angle slit or Grade 1 in more than 25% of the circumference?) 1 Yes 2 No 29
46. **Optic disc abnormality in either eye?**
- a. Pits 1 Yes 2 No 30
 - b. Colobomas 1 Yes 2 No 31
 - c. Drusen 1 Yes 2 No 32
 - d. Hemorrhage 1 Yes 2 No 33
 - e. Other (specify) 1 Yes 2 No 34
-
47. **Is asymmetry greater than 0.2 cup/disc ratio? 1 Yes 2 No 35**
48. **Are any of the answers to #45, #46, #47 "Yes"?**
1 Yes (Patient is ineligible) 36
2 No

Examination done by 37
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Humphrey 30-2 Visual Field Series

- Use OHTS certified perimeter only - see MOP Ch. 2 and 16 for VF protocol
- May use prestudy fields performed within 12 weeks of 1st QA visit date
- Two fields per eye must be reliable and normal
- Fax field printout to VFRC immediately. VFRC will respond in 24 hrs. by FAX
- Ship diskette and printout to VFRC ASAP
- Patients excluded for failing reliability indices may be reevaluated after 3 months

| | | | | | | |
|-----|-----------------------------------|---|-----------|---|----------------------|----|
| 49. | Date of 1st Field | <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"><input type="text"/> mm</div> <div style="text-align: center;"><input type="text"/> dd</div> <div style="text-align: center;"><input type="text"/> yy</div> </div> | OD | <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"><input type="text"/> mm</div> <div style="text-align: center;"><input type="text"/> dd</div> <div style="text-align: center;"><input type="text"/> yy</div> </div> | OS | 19 |
| | Field #1 - OD performed by | <input type="text"/> | | Field #1 - OS performed by | <input type="text"/> | 31 |
| 50. | Date of 2nd Field | <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"><input type="text"/> mm</div> <div style="text-align: center;"><input type="text"/> dd</div> <div style="text-align: center;"><input type="text"/> yy</div> </div> | | <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"><input type="text"/> mm</div> <div style="text-align: center;"><input type="text"/> dd</div> <div style="text-align: center;"><input type="text"/> yy</div> </div> | | 37 |
| | Field #2 - OD performed by | <input type="text"/> | | Field #2 - OS performed by | <input type="text"/> | 49 |
| 51. | Date of 3rd Field | <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"><input type="text"/> mm</div> <div style="text-align: center;"><input type="text"/> dd</div> <div style="text-align: center;"><input type="text"/> yy</div> </div> | | <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"><input type="text"/> mm</div> <div style="text-align: center;"><input type="text"/> dd</div> <div style="text-align: center;"><input type="text"/> yy</div> </div> | | 55 |
| | Field #3 - OD performed by | <input type="text"/> | | Field #3 - OS performed by | <input type="text"/> | 67 |

END08

Stereo Optic Disc Photography

- Ship Photos to ODRC within 1 week
- See MOP Ch. 2 and 15 for photography protocol
- May use prestudy photographs taken within 12 weeks of 1st QA visit date provided they meet protocol standards

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|-----|----------------------|---|-----------|---|-----------|----|
| 52. | Date of Photos | <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"><input type="text"/> mm</div> <div style="text-align: center;"><input type="text"/> dd</div> <div style="text-align: center;"><input type="text"/> yy</div> </div> | OD | <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"><input type="text"/> mm</div> <div style="text-align: center;"><input type="text"/> dd</div> <div style="text-align: center;"><input type="text"/> yy</div> </div> | OS | 19 |
| | Photographs taken by | <input type="text"/> | | | | 31 |

END09