





### OHTS Baseline/Randomization Visit: BR

➤ IOP is measured by two people  
-the OPERATOR aligns the mires  
-the RECORDER reads the dial

Patient ID:           9

Date:   /   /   19

mm                      dd                      yy

#### IOP Determination

- |  |  |  |   |   |    |
|--|--|--|---|---|----|
| 5.   | <b>Time of measurement</b> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> | <input type="checkbox"/> 1 am<br><input type="checkbox"/> 2 pm | <b>OD</b>                                       | <b>OS</b>                                       | 25 |
| 6.   | <b>1st IOP</b>   |  | <input type="text"/> <input type="text"/> mm Hg | <input type="text"/> <input type="text"/> mm Hg | 30 |
| 7.   | <b>2nd IOP</b>   |  | <input type="text"/> <input type="text"/> mm Hg | <input type="text"/> <input type="text"/> mm Hg | 34 |
| <b>Are the 1st and 2nd IOP determinations less than or equal to 2 mm Hg apart?</b><br><b>Yes:</b> Enter their average on line 9.<br><b>No:</b> Take a 3rd reading and enter on line 8. |  |  |   |   |    |
| 8.   | <b>3rd IOP</b>   |  | <input type="text"/> <input type="text"/> mm Hg | <input type="text"/> <input type="text"/> mm Hg | 38 |
| ➤ If a 3rd IOP is taken, enter the median (middle value) of 1st, 2nd, and 3rd IOP on line 9.   |  |  |   |   |    |
| 9.   | <b>IOP Result</b>  |  | <input type="text"/> <input type="text"/> mm Hg | <input type="text"/> <input type="text"/> mm Hg | 42 |
| ➤ Round to nearest whole number<br>➤ Round up when decimal is .5 or greater  |  |  |   |   |    |

Operator's Certification    Recorder's Certification    46

END02

This workbook is for clinic use only to help calculate goals for patients randomized to the medication group.

The treatment goals are as follows:

1. An IOP  $\leq$  24 mm Hg  
**and**
2. A 20% reduction in IOP from the average of the Qualifying IOP and the Baseline IOP result. The 20% reduction is not necessary if IOP  $\leq$  18mm Hg.

- |  |   |       |   |       |
|--|---|-------|---|-------|
|  | <b>OD</b>                                 |       | <b>OS</b>                                 |       |
| 1. Qualifying Assessment IOP average:<br>(average of 1st and 2nd determinations done during QA). | <input type="text"/> <input type="text"/> | mm Hg | <input type="text"/> <input type="text"/> | mm Hg |
| 2. Baseline/Randomization IOP result:  | <input type="text"/> <input type="text"/> | mm Hg | <input type="text"/> <input type="text"/> | mm Hg |
| 3. Final IOP result (average of #1 and #2):  | <input type="text"/> <input type="text"/> | mm Hg | <input type="text"/> <input type="text"/> | mm Hg |

➤ Round to nearest whole number  
➤ Round up when decimal is .5 or greater

### OHTS Baseline/Randomization Visit: BR

➤After IOP is taken, call Coordinating Center for randomization assignment

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Date:   /   /   19

mm                  dd                  yy

### Randomization Assignment

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10. Certification of Central Coordinator giving randomization:    25

11. Certification of Clinic Staff receiving randomization assignment:    28

12. Central Coordinator gives randomization assignment as follows:

<input type="checkbox"/> 1 Medication ➤Start one-eyed trial ➤Schedule IOP Confirmation visit in 4 ± 2 weeks	<input type="checkbox"/> 2 Close Observation ➤Schedule return visit in 6 months	31
13. Check the eye selected for one-eyed trial:		
<b>OD</b> <input type="checkbox"/> 1	<b>OS</b> <input type="checkbox"/> 2	32

➤Check which eye drop medication is selected for one-eyed trial on page 5.

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➤Dispense sufficient medication for 1 month

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Date:  /  /  19  
mm dd yy

Ocular Medication Prescribed

				OHBR02.05 1	
				Pt. ID 9	
	OD	OS	Dosage (# times daily)		Dosage (# times daily)
<b>14. Beta-Blockers</b>					
Betoptic S 0.25%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 25		
Betoptic 0.50%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 27		
Betagan 0.25%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 29		
Betagan 0.50%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 31		
Timoptic 0.25%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 33		
Timoptic XE 0.25%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 35		
Timoptic 0.50%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 37		
Timoptic XE 0.50%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 39		
OptiPranolol 0.30%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 41		
Ocupress 1.0%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 43		
<b>15. Epinephrine/Dipivefrin</b>					
Epifrin 0.5%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 45		
Epifrin 1.0%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 47		
Epifrin 2.0%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 49		
Propine 0.1%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 51		
<b>16. Alpha 2 Agonists</b>					
lopidine 0.5%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 53		
<b>17. Topical Carbonic Anhydrase Inhibitor</b>					
Trusopt	<input type="checkbox"/>	<input type="checkbox"/>	_____ 55		
<b>18. Miotics</b>					
Pilocarpine 0.5%*	<input type="checkbox"/>	<input type="checkbox"/>	_____ 25		
Pilocarpine 1.0%*	<input type="checkbox"/>	<input type="checkbox"/>	_____ 27		
Pilocarpine 2.0%*	<input type="checkbox"/>	<input type="checkbox"/>	_____ 29		
Pilocarpine 3.0%*	<input type="checkbox"/>	<input type="checkbox"/>	_____ 31		
Pilocarpine 4.0%*	<input type="checkbox"/>	<input type="checkbox"/>	_____ 33		
Pilocarpine 5.0%*	<input type="checkbox"/>	<input type="checkbox"/>	_____ 35		
Pilocarpine 6.0%*	<input type="checkbox"/>	<input type="checkbox"/>	_____ 37		
Pilopine gel 4.0%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 39		
*Check the brand name of pilocarpine used:					
Isopto Carpine		<input type="checkbox"/>	_____ 41		
Pilagan		<input type="checkbox"/>	_____ 42		
B&L Generic or Pilostat		<input type="checkbox"/>	_____ 43		
Carbachol 0.75%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 44		
Carbachol 1.50%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 46		
Carbachol 2.25%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 48		
Carbachol 3.0%	<input type="checkbox"/>	<input type="checkbox"/>	_____ 50		
<b>19. Other</b>					
Describe: _____	<input type="checkbox"/>	<input type="checkbox"/>	_____ 52		
<b>20. Systemic Carbonic Anhydrase Inhibitors</b>					
<i>(Open Arm only — approval of Study Chairman required before prescribing)</i>					
Diamox 125 mg.	<input type="checkbox"/>		_____ 54		
Diamox 250 mg.	<input type="checkbox"/>		_____ 55		
Diamox Sequels 500 mg.	<input type="checkbox"/>		_____ 56		
Neptazane 25 mg.	<input type="checkbox"/>		_____ 57		
Neptazane 50 mg.	<input type="checkbox"/>		_____ 58		

END04

**21. If patient is randomized to medication, but no medication is prescribed for one or both eyes check here:**

None - OD  None - OS

59

and explain: \_\_\_\_\_

Investigator's Certification    61  
END05