

OHTS Protocol Exemption Form: PE

Coordinating Center use only

Rec'd

Log'd

Chk'd

Entr'd

Patient ID:

Date: / /
mm dd yy

- Complete and mail this form to the Coordinating Center.
- Request will be reviewed by both the Medical Monitor and Study Chair.
- The Coordinating Center will notify the clinic of the decision.

Type of protocol exemption being requested:

1. Discontinue Goldmann Tonometry OD OS OU
 - Patient Unable; explain: _____
 - Patient Unwilling
 - 1a. Alternative IOP Measurement (Check only one)
 - Tonopen Other _____ None

2. Discontinue Humphrey 30-2 Visual Field OD OS OU
 - Patient Unable; explain: _____
 - Patient Unwilling
 - 2a. Alternative Visual Field Measurement (Check only one)
 - Other _____ None

3. Discontinue Optic Disc Photography OD OS OU
 - Patient Unable; explain: _____
 - Patient Unwilling
 - 3a. Alternative Disc Assessment (Check only one)
 - Other _____ None

_____ / /
OHTS Clinician Certification mm dd yy

For Coordinating Center Use Only

Approved? <input type="checkbox"/> Yes <input type="checkbox"/> No _____ OHTS Study Chair Signature	<input type="text"/> <input type="text"/> <input type="text"/> Certification	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> mm dd yy
Approved? <input type="checkbox"/> Yes <input type="checkbox"/> No _____ OHTS Medical Monitor Signature	<input type="text"/> <input type="text"/> <input type="text"/> Certification	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> mm dd yy
Final Decision <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> mm dd yy	
Endpoint Committee Recommendation <input type="checkbox"/> Yes		
Date Clinic Notified	<input type="text"/> <input type="text"/> <input type="text"/> Certification	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> mm dd yy